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6 MARKUP OF SUBCOMMITTEE VOTE ON OPIOID

7 LEGISLATION AND H.R. 5554

8 WEDNESDAY, APRIL 25, 2018

9 House of Representatives

10 Subcommittee on Health

11 Committee on Energy and Commerce

12 Washington, D.C.

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16 The subcommittee met, pursuant to call, at 1:00 p.m., in Room
17 2123 Rayburn House Office Building, Hon. Michael Burgess
18 [chairman of the subcommittee] presiding.

19 Members present: Representatives Burgess, Guthrie, Barton,
20 Upton, Shimkus, Blackburn, Latta, McMorris Rodgers, Lance,
21 Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson,
22 Collins, Carter, Walden(ex officio), Green, Engel, Schakowsky,
23 Butterfield, Matsui, Castor, Sarbanes, Lujan, Schrader, Kennedy,
24 Cardenas, Eshoo, DeGette, and Pallone (ex officio).

25

26 Staff present: Jennifer Barblan, Chief Counsel, Oversight
27 & Investigations; Mike Bloomquist, Staff Director; Adam Buckalew,
28 Professional Staff Member, Health; Daniel Butler, Staff
29 Assistant; Karen Christian, General Counsel; Kelly Collins, Staff
30 Assistant; Zachary Dareshori, Legislative Clerk, Health; Jordan
31 Davis, Director of Policy and External Affairs; Paul Eddatel,
32 Chief Counsel, Health; Margaret Tucker Fogarty, Staff Assistant;
33 Adam Fromm, Director of Outreach and Coalitions; Ali Fulling,
34 Legislative Clerk, Oversight & Investigations, Digital Commerce
35 and Consumer Protection; Caleb Graff, Professional Staff Member,
36 Health; Jay Gulshen, Legislative Associate, Health; Zach Hunter,
37 Director of Communications; Peter Kielty, Deputy General Counsel;
38 Ed Kim, Policy Coordinator, Health; Caprice Knapp, Fellow,
39 Health; Ryan Long, Deputy Staff Director; Drew McDowell,
40 Executive Assistant; James Paluskiewicz, Professional Staff,
41 Health; Mark Ratner, Policy Coordinator; Kristen Shatynski,
42 Professional Staff Member, Health; Jennifer Sherman, Press
43 Secretary; Danielle Steele, Counsel, Health; Austin Stonebraker,
44 Press Assistant; Josh Trent, Deputy Chief Health Counsel, Health;
45 Evan Viau, Legislative Clerk, Communications & Technology; Hamlin
46 Wade, Special Advisor, External Affairs; Jacquelyn Bolen,
47 Minority Professional Staff; Michael Budros, Minority Health
48 Fellow; Jeff Carroll, Minority Staff Director; Elizabeth Ertel,
49 Minority Deputy Clerk; Waverly Gordon, Minority Health Counsel;

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50 Tiffany Guarascio, Minority Deputy Staff Director and Chief
51 Health Advisor; Una Lee, Minority Senior Health Counsel; Dan
52 Miller, Minority Policy Analyst; Rachel Pryor, Minority Senior
53 Health Policy Advisor; Tim Robinson, Minority Chief Counsel;
54 Samantha Satchell, Minority Policy Analyst; Andrew Souvall,
55 Minority Director of Communications, Outreach and Member
56 Services; and Kimberlee Trzeciak, Minority Senior Health Policy
57 Advisor.

58 Mr. Burgess. I would ask all of our guests to take their
59 seats and call the subcommittee to order. I am going to recognize
60 myself three minutes for an opening statement.

61 Today's markup is a significant step in the subcommittee's
62 progress in addressing the opioid epidemic facing our nation. As
63 we mark up these 63 bills we will be making substantial headway
64 in the fight against this crisis that is tragically taking over
65 115 American lives per day.

66 Many of these bills are a product of a bipartisan effort and
67 compromise. Taken together, the bills before us will improve
68 access to care for individuals suffering from substance abuse
69 disorder. They will also provide our healthcare system with
70 tools and resources it needs to care for patients and help prevent
71 future misuse of the product.

72 Throughout this process we have engaged members, providers,
73 insurance plans, patient advocates, officials at federal
74 agencies, and will continue to do so. Some of the bills today
75 remain in discussion draft form, and that is intentional,
76 signaling our commitment to continue working with members and
77 stakeholders and to get the technical details right so that our
78 agencies can implement these promising solutions in a timely
79 manner.

80 Thanks for the work of members of this subcommittee these
81 bills are on track to make a positive impact when they are signed

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82 into law by providing help where it is most needed and helping
83 ensure taxpayer dollars are spent in a responsible manner.

84 The crisis is devastating our country, undermining our
85 social structures, and eroding economic productivity and
86 opportunity. This subcommittee and the full Energy and Commerce
87 Committee are committed to turning the tide in our fight against
88 this crisis. This fight is not abstract. It is a fight against
89 a known enemy. And it is personal because it is a battle for the
90 heart and soul of too many of our friends, neighbors, and
91 communities.

92 We have reached this point because we have been in the fight
93 for months. Last October we held a member day where members on
94 and off the committee offered their ideas and solutions to combat
95 the opioid crisis. February the subcommittee reviewed more than
96 a half dozen bills aimed at helping communities balance
97 enforcement and patient safety. In March we reviewed more than
98 two dozen bills over two days focusing on improving public health
99 and prevention efforts. This month we reviewed bills focused on
100 leveraging Medicaid and Medicare authorities to help patients
101 served by those programs.

102 And just last week we had the privilege to listen to parents
103 in a survivor group, parents who have been so tragically impacted
104 by this opioid epidemic.

105 This is a work in progress. We are going to continue to work

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106 on these bills and receive feedback from stakeholders and
107 technical assistance from the Administration and the
108 Congressional Budget Office. I am pleased that this subcommittee
109 will report a promising collection of bills to the full committee.

110 Just last week the country laid to rest former First Lady
111 Barbara Bush. And part of Barbara Bush's legacy will forever be
112 the embrace of a child with HIV/AIDS at an AIDS clinic. That
113 simple act began the process of destigmatization of that disease,
114 which ultimately led to much more promising solutions than were
115 available at the time. I believe this markup today will also help
116 alleviate some of the stigma surrounding this problem. And
117 removal of that stigma is going to be critical in reaching a
118 solution.

119 Finally, I want to mention that we are marking up H.R. 5554,
120 a bill to reauthorize user fee programs for animal drugs and
121 generic animal drugs. Timely consideration and completion of
122 reauthorizing these important programs is important for American
123 families and businesses that rely on the vital functions of the
124 U.S. Food and Drug Administration's Center for Veterinary
125 Medicine.

126 I want to thank the members of our subcommittee and other
127 members who have put up bills for consideration today. We
128 appreciate your hard work, we appreciate the work of staff, and
129 the willingness to put forth creative ideas in combating this

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130 public health crisis.

131 I will now yield three minutes to the ranking member of the
132 subcommittee, Mr. Green of Texas.

133 Mr. Green. Thank you, Mr. Chairman.

134 The CDC reported that over 42,000 Americans died from opioid
135 overdoses in 2016, a dramatic increase from just a few years ago.
136 This is an epidemic that's impacting communities throughout the
137 United States that must be reversed as soon as possible. We have
138 heard from federal agencies, concerned stakeholders, parents of
139 children who died from opioids over three hearings and a
140 roundtable meeting, last Friday I believe.

141 The main concern we consistently heard was the need for
142 greater access to care and removing the existing barriers that
143 prevent Americans from receiving the treatment needed to overcome
144 opioid abuse. During this process I am concerned, and mentioned
145 it, that as a committee we, I am concerned we are putting quantity
146 over quality. We will be considering 64 separate bills,
147 discussion drafts during today's markup, an unprecedented number
148 during my time on the Energy and Commerce Committee.

149 The fact is, many of these discussion drafts have not been
150 fully vetted by the staff, stakeholders, nor received technical
151 assistance from the appropriate agencies. Before we proceed with
152 the full committee markup we must be confident that these bills
153 have been fully vetted before we receive our committee's blessing.

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154 Our committee must conduct this process with a laser eye
155 focus on expanding high quality, affordable treatment, and
156 ensuring the necessary continuum of care for Americans struggling
157 with opioid addiction, especially for vulnerable populations such
158 as postpartum mothers, foster children, and Americans leaving our
159 correctional system. Expanding treatment and care will take
160 additional federal resources. I hope the majority will seriously
161 consider authorizing the funds necessary to help expand our
162 nation's treatment of infrastructure, and make sure Americans
163 suffering from opioid abuse have the necessary coverage.

164 Two bills that I believe that would make a difference are
165 the Comprehensive Opioid Recovery Centers Act, H.R. 5237; and the
166 Misuse/Abuse discussion draft.

167 The Comprehensive Opioid Recovery Centers Act which I am
168 proud to introduce with Representative Guthrie from Kentucky
169 would fund designated treatment centers where individuals would
170 receive comprehensive patient-centered care for opioid addiction
171 and other substances disorders. This bill focuses on developing
172 model practices for treatment and recovery that can be duplicated
173 nationwide.

174 The Misuse or Abuse discussion draft will clarify the FDA's
175 authority to take on consideration of the potential for risk and
176 abuse and misuse when making approval decisions. This is an
177 important and unique consideration for FDA when approving

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178 controlled substances. I believe this is already a key part of
179 our effort to combat the opioid crisis. And I ask for the
180 committee's support.

181 And I thank you and I yield back my 15 seconds left.

182 Mr. Burgess. The gentleman yields back. The chair thanks
183 the gentleman.

184 The chair yields one minute to the gentleman from Michigan,
185 the former chairman of the full committee, one minute for an
186 opening statement, please.

187 Mr. Upton. Well, thank you, Mr. Chairman. I appreciate
188 your leadership on this and I appreciate every member on both sides
189 of the aisle. I think you have taken good deliberative action
190 to take many of our good ideas to move forward.

191 Everyone here has sat with real people who have experienced
192 the real pain that has impacted their lives forever. And we know
193 we can make a difference. And that's what these bills, what these
194 many bills will do. So I appreciate that they are all bipartisan,
195 that we can work together and we can tell our constituents and
196 folks all across the country that, yes, we have heard them and
197 we want to do something about it.

198 For me, I have got one particular bill here that is of major
199 importance and that is we asked the questions of the
200 Administration, the FDA, and the NIH, what is it that we can do
201 to take down some of those roadblocks so we can actually develop

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202 non-addictive painkilling drugs? They told us. And Debbie
203 Dingell and I introduced that legislation. And it is important
204 that we move it through today and get it to the floor and to send
205 it to the President.

206 I yield back.

207 Mr. Burgess. The gentleman yields back. The chair thanks
208 the gentleman.

209 The chair recognizes the ranking member of the full
210 committee, Mr. Pallone, three minutes for an opening statement,
211 please.

212 Mr. Pallone. Thank you, Mr. Chairman.

213 Today's markup will mainly focus on proposed legislation to
214 address the opioid epidemic. And this complex public health
215 crisis facing our nation requires thoughtful, measured solutions.

216 While I support a bipartisan process to address this crisis,
217 I am troubled by the unprecedented number of bills, 63 in today,
218 and the chairman's extremely hasty time frame to pass opioid
219 legislation. Dr. Burgess said in the beginning that this is a
220 work in progress, but I think that it is too much of a work in
221 progress in my opinion at this point to actually be trying to move
222 some of these bills.

223 We can all agree that action must be taken to stymie the
224 opioid overdose deaths ravaging our country. But taking the
225 wrong action because we are not spending the appropriate amount

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226 of time to get these policies right could have the very serious
227 consequences of making things worse. And I have urged the
228 chairman to slow this process down, to choose quality over
229 quantity. And today I want to repeat that caution and remind this
230 entire subcommittee that there is no margin for error in a public
231 health crisis of this magnitude.

232 Due to the rushed time line, many of these bills are works
233 in progress and still in discussion draft form. These forced time
234 constraints mean that some bills suffer from lack of technical
235 assistance from our federal agencies, or a CBO analysis.
236 Additionally, and equally important, stakeholders have not had
237 the opportunity to adequately evaluate these bills or weigh in
238 on their impact.

239 At the end of the day I am evaluating, and I think most
240 committee Democrats will evaluate this bill, these bills, based
241 on two principles:

242 One, whether the proposal meaningful improves access to
243 treatment for opioid use disorders, or;

244 Two, whether the proposal helps to prevent people from
245 getting addicted to opioids in the first place.

246 And I want to mention that as this process has moved forward
247 we have not yet had a conversation about offsets. The reality
248 is that meaningful policy in this space must cost money, and
249 agreement on appropriate offsets that do not harm people,

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250 including the very people that we may be trying to help, is a
251 critical component needed in order for me to support these bills
252 moving forward.

253 So I just hope to continue working with my colleagues on
254 today's list of bills to address the opioid crisis. But many of
255 the policies are far-reaching, complex changes to our federal
256 health programs. So I want to be clear that I intend to oppose
257 any bill that does not improve access to treatment, has nothing
258 to do with addressing the opioid epidemic or could potentially
259 worsen the crisis, or is simply not ready in the time that we have
260 been allotted. Because I think it would be irresponsible to push
261 these policies forward without understanding their full impact.

262 Now, Mr. Chairman, I know you did say the works are in
263 progress. And I understand that you want to reach out to us. But
264 I, we are going to point out today exactly where we have problems
265 with these things or think that they need more work. And in some
266 cases we will have to oppose the bills because we think that they
267 really need a lot more work, or perhaps they shouldn't move forward
268 at all.

269 So I want to thank you. And I yield back.

270 Mr. Burgess. The chair looks forward to your counsel.

271 The chair recognizes the gentleman from Oregon, the chairman
272 of the full committee, Mr. Walden, three minutes for an opening
273 statement, please.

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274 The Chairman. Well, thank you, Dr. Burgess. I want to
275 thank you and Mr. Green for your leadership on this issue.

276 As you know, we started an investigation of the death and
277 dying in our communities due to overdoses of opioids more than
278 a year ago. We have had multiple meetings in this committee. We
279 have had roundtables in our districts. We had a member day last
280 fall where more than 50 members of the House came and presented
281 their ideas, many of which we are bringing forward here.

282 We have had four sets of hearings on the legislation and the
283 issues attendant to them.

284 Nine point six people will die in the next hour because of
285 overdose from opioids; 41 will show up in emergency rooms due to
286 overdose. I think it is the height of irresponsibility to drag
287 and delay, and that is why we are moving forward.

288 Now, we could have one bill before us, and it would be about
289 this big, and we would have them all in there, and I don't know
290 what your argument would be. We have looked at these
291 individually. We will continue to work with members moving
292 forward. It is our job to move forward.

293 This committee passed the 21st Century Cures legislation a
294 few years ago under the leadership of Mr. Upton and Ms. DeGette.
295 That put over a billion dollars into our communities to help
296 address this.

297 We came back in the omnibus appropriation bill with another

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298 \$6 billion for mental health and opioid addiction and treatments.

299 And now we are moving forward with I think really thoughtful,
300 well-considered pieces of legislation in the markup that we are
301 having today.

302 And I don't know, we had a victims panel last Thursday.
303 Started at 10:30 in the morning and ended at a quarter of 1:00.
304 And these individuals came and they told us about their loved ones
305 who had passed away. And I appreciate Mr. Green being here and
306 the Republican members who were here. I think all of us left
307 feeling like we had been to multiple funerals.

308 And we talked a lot about the issues that are before us today
309 in legislation. We sought their input and guidance on these, as
310 we have the DEA, as we have medical providers, as we have the folks
311 from Medicare and Medicaid. And you know the series of hearings.
312 It is time for us to act, not to drag our feet and delay and wait
313 another day and another 41 or 116 people dying. Today is the day
314 we will move forward. We will do our work. We will consider
315 these bills.

316 And I hope our members will walk away from this proceeding
317 and the one that will follow with the full committee knowing we
318 are saving lives, we are keeping our promise to our constituents,
319 and we are going to leave this country in better shape than it
320 is in now.

321 With that, I yield back.

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322 Mr. Burgess. The gentleman yields back. The chair thanks
323 the gentleman.

324 The chair recognizes the gentleman from New York, Mr. Engel,
325 one minute for an opening statement.

326 Mr. Engel. Thank you, Mr. Chairman.

327 The opioid epidemic has touched every corner of our country.
328 I represent part of Westchester County, New York, where 124 people
329 died due to opioids in 2016. And in the Bronx, New York, which
330 I also represent, more New Yorkers died of overdoses there than
331 any other New City borough.

332 Too many American families are suffering and they need
333 solutions. I am pleased to have co-authored two of the solutions
334 we are considering today. The Poison Center Network Enhancement
335 Act, which I have introduced with Congresswoman Brooks, will
336 authorize the nation's Poison Center Program for an additional
337 5 years. Since 2011, U.S. Poison Centers have handled nearly 200
338 cases per day involving opioid misuse. Poison Center experts
339 have also helped identify trends in the epidemic, and educated
340 Americans about this crisis.

341 The second bill is the Results Act, which I have introduced
342 with Congressman Stivers, that will provide needed guidance for
343 applicants seeking federal funding to treat or prevent mental
344 health or substance use disorders.

345 I believe both of these bills will play an important role

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346 in our response to this epidemic, and I am pleased to see them
347 moving forward.

348 I want to identify, though, with the remarks that Mr. Pallone
349 made that there are so many bills that we feel haven't been vetted
350 or scrutinized. And I think it would do us better to do that
351 before we vote on it.

352 Thank you, Mr. Chairman.

353 Mr. Burgess. The chair thanks the gentleman. The
354 gentleman yields back.

355 The chair recognizes the gentlelady from Tennessee, one
356 minute for an opening statement, please.

357 Mrs. Blackburn. Thank you, Mr. Chairman.

358 I am so appreciative of the time that we are spending on these
359 bills and the work that the committee staff, and our staff, our
360 teams, the agencies have put into making certain that we address
361 the situation that is in front of us. When I was a state senator
362 in Tennessee I did a lot of work with the drug courts and with
363 making certain that moms and their children could be reunited and
364 work through the issues associated with both addiction and
365 recovery.

366 And we are continuing this. Last year we passed CARA. And
367 that made some great strides and put some good resources forward.
368 And today is our opportunity to really build on that and to look
369 in totality at our local, our state, our federal, how this is going

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370 to work together so that we can stop the flow of these drugs in
371 our communities.

372 I am so grateful for the markup on my bill and working with
373 the FDA to stop these drugs from coming into our communities
374 through the international mail facilities. Looking forward to
375 work together.

376 And I yield back.

377 Mr. Burgess. The chair thanks the gentlelady. The
378 gentlelady yields back.

379 The chair observes that there are a series of votes on the
380 floor. The subcommittee obviously could not convene in the
381 morning because of the joint session of Congress that was
382 proceeding on the House floor.

383 Let me recognize the gentlelady from Illinois for one minute,
384 after which time we will recess until votes are over. You are
385 recognized for one minute, Ms. Schakowsky.

386 Ms. Schakowsky. Mr. Chairman, as we sit here today debating
387 how to best address the opioid epidemic the Administration has
388 waged war on the very lifeline for so many with substance abuse
389 disorders, Medicaid. Right now Medicaid provides coverage for
390 40 percent of those with opioid disorder. The Trump
391 administration is encouraging work requirements for Medicaid
392 enrollees.

393 A PriceWaterhouseCoopers study found that 1.7 million people

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394 would lose coverage in the ten states that are considering or have
395 work requirements. The Affordable Care Act repeal attempts would
396 have cut Medicaid by hundreds of millions of dollars. And
397 Medicaid cuts were included in the President's FY 2019 budget.

398 Cutting Medicaid hurts people suffering from substance abuse
399 disorder. Any attempt to do so should be called what it is: making
400 the opioid epidemic worse.

401 And I yield back.

402 Mr. Burgess. The chair thanks the gentlelady. The
403 gentlelady yields back.

404 We are going to hear from Mr. Latta and Ms. Matsui.

405 Mr. Latta, you are recognized for one minute for an opening
406 statement.

407 Mr. Latta. Thank you, Mr. Chairman.

408 Through countless meetings, roundtables, and forums I have
409 held in my district, and through the subcommittee's hearings I
410 have learned that the road to prevention, treatment, and recovery
411 is multi-faceted, and that more needs to be done to help those
412 who are hurting. Many of the bills before us today are steps in
413 the right direction.

414 My bill, the INFO Act, will assist in finding answers and
415 help individuals overcome addiction. The INFO Act creates a
416 publish dashboard consisting of comprehensive information and
417 data on nationwide efforts to combat the opioid crisis. This will

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418 allow advocates and healthcare providers to better access federal
419 funding, opportunities, data on opioid abuse and best practices
420 for treatment.

421 In the 12-month period ending in June of last year, over 5,200
422 lives were lost in Ohio due to overdoses. That is a 39 percent
423 increase from the previous year, and three times the national
424 average. I see this heartbreaking tragedy occur in my home state
425 and across the nation. And that is why I can't emphasize how
426 important it is for us to act now.

427 And with that, Mr. Chairman, I yield back.

428 Mr. Burgess. The chair thanks the gentleman. The
429 gentleman yields back.

430 The chair recognizes the gentlelady from California, Ms.
431 Matsui, for one minute for an opening statement, please.

432 Ms. Matsui. Thank you, Mr. Chairman.

433 Our committee has a daunting yet absolutely essential task
434 before us today, to make policy changes that address the opioid
435 epidemic without creating unintended consequences. This effort
436 requires our careful attention. We have all heard stories from
437 constituents about the devastating toll that this crisis is having
438 on families. But not everyone's experience of substance abuse
439 disorder is the same, which means we have to look at this epidemic
440 from many different angles.

441 For many patients, access and quality treatment, whether

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442 medication-specific treatment for opioid use disorder, or mental
443 health services for an underlying mental illness continues to be
444 an obstacle. I believe our technology has the power to raise some
445 of those gaps in access and to improve the coordination and
446 integration of care.

447 I am pleased to lead three bills today that leverage
448 technology to advance treatment for patients suffering from an
449 opioid use disorder. And I do look forward to working diligently
450 on these bills, and others, with my colleagues.

451 Thank you, and I yield back.

452 Mr. Burgess. The chair thanks the gentlelady. The
453 gentlelady yields back.

454 At this point we will recess until immediately after votes.
455 The subcommittee stands in recess.

456 [Recess.]

457 Mr. Burgess. I call the subcommittee back to order.

458 When the committee adjourned we had just heard from Ms.
459 Matsui for an opening statement. It is now in order to recognize
460 Mr. Bilirakis from Florida, one minute for an opening statement,
461 please.

462 Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it.

463 Again, industry standards maximize the reliability of
464 products, materials, and services people use every day. In
465 healthcare, standards help direct and maintain safe and

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466 medically-effective practices. Without standards, quality
467 outcomes and, ultimately, patient safety can be jeopardized.
468 That is why I am pleased to see the Ensuring Access to Quality
469 Sober Living Act, a bill I helped introduce, being marked up today.

470 In addition, I am glad we are considering a discussion draft
471 of Mandatory Lock-In Programs to require prescription drug plan
472 sponsors under the Medicare program to establish drug management
473 programs for at-risk beneficiaries. I look forward to continuing
474 the great work of the subcommittee and advancing these bipartisan
475 measures.

476 I thank you, and I yield back.

477 Mr. Burgess. The chair thanks the gentleman. The
478 gentleman yields back.

479 The chair now recognizes the gentlelady from Florida, Ms.
480 Castor, for one minute for an opening statement, please.

481 Ms. Castor. Thank you, Mr. Chairman.

482 Colleagues, I think the process here is very poor and I think
483 it does a disservice to folks that are suffering from the opioid
484 epidemic across America. To have 63 bills, many that are not even
485 introduced, on an agenda for markup is not the way to craft policy.

486 But it pales in comparison with the real problem here, and
487 that is this whole package fails to meet the challenge of the
488 opioid epidemic we are confronting in America today, responsible
489 for nearly as many deaths per year as the AIDS epidemic was at

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490 its peak. We now have a lack of consistent funding for our
491 providers back home. What we need to craft is something along
492 the lines of the Ryan White response to the AIDS epidemic for the
493 opioid epidemic in America so patients, and families, and
494 providers can rely on that consistent funding. We can make a
495 difference.

496 Many of the experts who testified in front of the committee
497 called for the same thing. This package fails in that regard.
498 And I hope we can talk more about that today.

499 I yield back.

500 Mr. Burgess. The chair thanks the gentlelady.

501 The chair recognizes the gentleman from Illinois, Mr.

502 Shimkus, one minute for an opening statement.

503 Mr. Shimkus. Thank you, Mr. Chairman.

504 I just wanted to point out to and thank former Chairman Upton
505 and Diana DeGette. I have got information that Illinois
506 Department of Human Services received a 2-year grant, \$16 million
507 for each year, that is \$32 million for the opioid crisis.

508 There is also another \$2 million federal grant that the
509 Illinois Department of Public Health has received to train rural
510 underserved areas, some in the counties that I represent.

511 So for a -- that is for a 2-year budget that is \$34 million
512 from a bill that, bipartisan bill that we passed out of this
513 committee. In Illinois, and I think across the country, that is

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514 real money. And I want to just highlight that as we go down this
515 debate about what we are doing, what we are not doing enough of.
516 This is a success story that is -- we hope to build on. And I
517 yield back.

518 Mr. Burgess. The chair thanks the gentleman. The
519 gentleman yields back.

520 The chair is now prepared to yield to the minority side to
521 the gentlelady from California, Ms. Eshoo, for one minute.

522 Ms. Eshoo. Thank you, Mr. Chairman.

523 There is no doubt that what we are discussing today, part
524 of a long, winding road, discussions here at the subcommittee on
525 the opioid crisis in our country. Countless lives being lost.
526 The chairman of the full committee went through all of that.

527 But I have to say that this is one of the toughest
528 preparations that I have had to go to in order to be prepared for
529 the markup. I don't ever remember having 34 bills being
530 discussion drafts, and that they are bills that, as far as I could
531 tell, have not yet even been introduced.

532 This subject matter requires so much more and so much better.
533 We don't know what the pay-fors are. We haven't had full analysis
534 from the agencies that are a part of, would be a part of
535 implementation and are expert in this. So it is this is really
536 a very mixed-up package.

537 And I don't know if others had a hard time going through to

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538 prepare for this, but I certainly did. And I have been around
539 for a long time. So I don't think we are doing justice to the
540 issue. And that is what troubles me.

541 I think we would be much better off taking up the bills that
542 are non-controversial, start with that and voice vote them, and
543 put off those that have not yet been introduced, and maybe take
544 up the one-third that are bipartisan. But this is not, this is
545 not a markup that has the imprimatur of legislative excellence
546 to it. And I am sorry to say that, but it just isn't.

547 Can anyone tell me when we have had bills that we are
548 considering for markup discussion drafts?

549 Mr. Burgess. I can share with you the gentlelady's time has
550 expired.

551 Ms. Eshoo. Thank you. I would like to know the answer.

552 Mr. Burgess. I will now recognize the gentleman from New
553 York, one minute for an opening statement, please.

554 Mr. Collins. Thank you, Mr. Chairman.

555 I applaud the collaborative and bipartisan work of this
556 committee and of Ways and Means on legislation building on the
557 policies and initiatives we implemented with CARA and 21st Century
558 Cures. In particular, I would like to highlight two bills I am
559 proud to support: the Eliminating Opioid-Related Infectious
560 Diseases Act of 2018 would expand the CDC's surveillance of
561 injection drug-related infectious diseases. This bill is widely

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562 supported by patients, scholars, city health officials, and more.
563 And I thank Mr. Lance and Mr. Kennedy for championing this effort.

564 I also want to recognize my fellow New Yorker, Mr. Jeffries,
565 for his leadership in the Synthetic Drug Awareness Act. I am
566 proud that we worked together to advance this bill and produce
567 a study of the public health effects of drugs on America's youth.

568 Finally, I would like to remind the committee and those
569 watching that April 28th is Drug Take Back Day.

570 Thank you, Mr. Chairman, I yield back.

571 Mr. Burgess. The chair thanks the gentleman. The chair
572 recognizes the gentlelady from Colorado, Ms. DeGette, one minute
573 for your opening statement.

574 Ms. DeGette. Thank you. Thank you, Mr. Chairman. And
575 certainly Mr. Upton and I appreciate all of the kudos going to
576 21st Century Cures.

577 I would just remind people we worked on that bill for 3 years
578 with everyone in a bipartisan way on this committee. We ended
579 up passing the comprehensive bill unanimously through the
580 committee, which everybody is justly proud of. We included \$2
581 billion in that bill for the opioid abuse as well as the other
582 things.

583 I am sorry to say this endeavor today just doesn't meet those
584 high standards of the committee. I think that we should -- it
585 is both too slow and too fast because, it is, because this

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586 committee reacted much too slowly to the opioid crisis. We have
587 been having hearings in the Oversight and Investigations
588 Subcommittee for 3 years on this. And then what did we do,
589 recognizing that time was a-wasting? We suddenly threw up 63
590 bills, half of them not even yet introduced.

591 Over here we are wondering how can you mark up a bill that
592 hasn't even been introduced?

593 So I would be happy to work with my colleagues to come up
594 with a comprehensive bipartisan solution with some real money to
595 supplement the money we put in Cures. That is what the opioid
596 patients of this country deserve.

597 Thank you, Mr. Chairman.

598 Mr. Burgess. The chair thanks the gentlelady. The
599 gentlelady yields back.

600 The chair recognizes the gentleman from Georgia, Mr. Carter,
601 one minute for an opening statement, please.

602 Mr. Carter. Thank you, Mr. Chairman.

603 I am delighted to be here today to take a major step in marking
604 up this critical package of legislation. There is not a state
605 or district that hasn't been touched by this problem. A hundred
606 and fifteen people die in this nation every day because of
607 prescription opioid overdose.

608 My home state of Georgia stands among the top 11 states in
609 the country with the most prescription opioid deaths according

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610 to the Georgia Department of Public Health. These are statistics
611 that need to be urgently addressed. We have made great progress
612 with the passage of the Comprehensive Addiction and Recovery Act,
613 but we have the opportunity to do more.

614 I believe there are numerous challenges that our community
615 healthcare providers and community leaders face. And these
616 pieces of legislation will help them address many of those
617 challenges. As a lifelong healthcare professional, I believe the
618 key to filling any successful prescription is education. I
619 co-authored legislation included in this markup that will give
620 pharmacists additional tools to help detect fraudulent
621 prescriptions.

622 It is important to remember in the midst of this opioid
623 epidemic that there are chronic pain patients in this country who
624 still need to access their prescription pain medication.

625 I would like to commend the committee for the cooperation
626 of bipartisanship on these bills, and look forward to seeing this
627 package on the President's desk.

628 Thank you, Mr. Chairman, I yield back.

629 Mr. Burgess. The chair thanks the gentleman. The
630 gentleman yields back.

631 The chair would now recognize the gentleman from North
632 Carolina, Mr. Butterfield, for one minute for an opening
633 statement.

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634 Mr. Butterfield. Thank you, Mr. Chairman. I won't take the
635 full time, Mr. Chairman.

636 But I want to pick up where Ms. Eshoo left off a few minutes
637 ago, Mr. Chairman. And I haven't been here as long as the
638 gentlelady has, but I have certainly been here for 14 years. And
639 to my recollection I do not ever remember this committee or any
640 other committee marking up 63 bills that have not been introduced.

641 And so I just want to go on the record expressing my
642 disapproval and dissatisfaction with the way we are conducting
643 this. I think there is a better way.

644 I don't know what I will say to my constituents when I go
645 home this weekend and they ask the question how do you mark up
646 a bill that has not been introduced? And I don't have a, I don't
647 have a clear for, for any of them.

648 But I just had to get it out, Mr. Chairman. And I will yield
649 to anyone else who might want to take the time.

650 Ms. Castor. Well, and I would hope -- thank you, Mr.
651 Butterfield -- what the committee could work on is something along
652 the likes of the Ryan White Act. Many said Congress was too slow
653 to act during the AIDS epidemic and public health crisis. We have
654 an opportunity now to provide that consistent and dependable
655 funding and programmatic, everything we have learned on
656 expertise, from experts here, to provide something along the lines
657 of Ryan White to meet the challenge of this opioid public health

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658 epidemic.

659 And I yield back.

660 Mr. Burgess. The chair thanks the gentlelady and the
661 gentleman for -- -

662 Mr. Butterfield. I yield back, Mr. Chairman.

663 Mr. Burgess. -- yielding.

664 Are there any other members who need time for opening
665 statements? The chair recognizes the gentleman from New Mexico
666 for one minute.

667 Mr. Lujan. Thank you, Mr. Chairman. And thank you so much
668 for this important markup.

669 Just to continue where Representative Castor left off there,
670 not only is looking to Ryan White a good idea, we actually have
671 legislation that is built off of the Ryan White model to allow
672 us to move forward in a comprehensive way when it comes to doing
673 all that we can to address this opioid epidemic.

674 But, Mr. Chairman, what I wanted to share today is I very
675 much appreciate and share the sentiment of the words of our
676 chairman, of Mr. Walden. With all of our constituents and
677 families, all the loved ones that we have lost, we have to act.
678 There are some important pieces of legislation that will be
679 considered today. What I think we all believe, though, is that
680 there is no reason that these bills should not be bipartisan as
681 well.

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682 This is an issue that is not red nor blue. This is an issue
683 that is important to us in all parts of America, in big towns,
684 small towns, and rural parts of America. And I am certainly
685 hopeful that as we go through this process and we are looking at
686 bills today, we are looking at bills in the full committee markup
687 going to the floor, what might be conference committee as well
688 in working with the House and Senate, that we get this right.
689 There is too much at stake for there to be partisan disagreements
690 on these issues with what is at stake.

691 And so I am hopeful, Mr. Chairman, as we continue that we
692 keep that in mind to get this right. And I thank you for the
693 indulgence of the time, sir.

694 Mr. Burgess. The gentleman's time has expired. The
695 gentleman yields back.

696 The chair reminds the gentleman the journey of a thousand
697 miles starts with the first step.

698 The chair recognizes the gentleman from New Jersey, Mr.
699 Lance, one minute for an opening statement.

700 Mr. Lance. Thank you, Mr. Chairman. I yield to the
701 distinguished chairman of the full committee.

702 The Chairman. Thank you, Mr. Lance. And I appreciate the
703 gentleman's comments from New Mexico.

704 Amanda Beatrice Gray. To my colleagues on the other side
705 of the aisle, had you been here for the victims' panel last

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706 Thursday you would have met Amanda Beatrice Gray's parents. You
707 would maybe better appreciate why we are moving forward with these
708 bills. Virtually all of them are bipartisan, either in bill form
709 or in discussion draft. This committee frequently at the
710 subcommittee level works on discussion drafts.

711 Nine point six people will die this hour. Forty-one will
712 go to emergency rooms in overdose. We need to act. We could have
713 easily combined this into one bill, as I said, but we had 50 members
714 come before our committee with their ideas. And so over the
715 course of multiple hearings we have taken up their ideas and now
716 we bring them forward in regular order before this subcommittee
717 so we can vet them. There will be time before the full committee
718 to improve upon them. But we need to move forward so that there
719 aren't more victims like Amanda.

720 And the children of the other parents who were here last
721 Thursday, who pled with us not to delay, not to wait but to move
722 forward.

723 I yield back.

724 Mr. Burgess. The chair thanks the gentleman. The chair
725 thanks the gentleman from New Jersey for yielding to the chairman
726 of the full committee.

727 Are there other members seeking time for opening statements?

728 Seeing none, the chair calls up H.R. 3331 and asks the clerk
729 to report.

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730

[The bill follows:]

731

732

***** COMMITTEE INSERT 1 *****

733 Mr. Viau. H.R. 3331, to amend Title XI of the Social
734 Security Act to promote testing of incentive payments for
735 behavioral health providers for adoption and use of certified
736 electronic health record technology.

737 Mr. Burgess. Without objection, the first reading of the
738 bill is dispensed with and the bill will be open for amendment
739 at any point.

740 So ordered.

741 Are there bipartisan amendments to the bill?

742 [No response.]

743 Mr. Burgess. Are there other amendments?

744 Would any member wish to be recognized to be heard on the
745 bill? The chair recognizes the gentleman from -- For what purpose
746 does the gentleman from Oklahoma seek recognition?

747 Mr. Mullin. I move to strike the last word.

748 Mr. Burgess. The gentleman is recognized for five minutes.

749 Mr. Mullin. I want to take a few moments to discuss H.R.
750 3331, introduced by my friend and colleague Congresswoman Matsui
751 and Congresswoman Jenkins.

752 As a senior member of the Ways and Means Subcommittee, this
753 legislation would authorize the Center for Medicare, Medicaid
754 health and IT incentives demonstration for psychiatric hospitals,
755 community and mental health centers, social workers,
756 psychiatrists, and addiction treatment providers. I understand

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757 that H.R. 3331 has a zero score for the CBO, which is good for
758 us.

759 As many of you know, I strongly believe that we should be
760 using the latest technology to both prevent opioid addiction and
761 improve substance abuse treatment. This bill helps move us in
762 that direction.

763 So I commend my colleagues Representative Jenkins and
764 Representative Matsui for their leadership in introducing this
765 important bill. And, Mr. Chairman, I encourage all my colleagues
766 to suppose this bill.

767 And I yield back.

768 Mr. Burgess. The gentleman yields back. The chair thanks
769 the gentleman.

770 Is there any other member that --

771 Ms. Matsui. Mr. Chairman.

772 Mr. Burgess. For what purpose does the gentlelady from
773 California seek --

774 Ms. Matsui. I move to strike the last word.

775 Mr. Burgess. The gentlelady is recognized for five minutes.

776 Mr. Matsui. Mr. Chairman, I rise in support of H.R. 3331,
777 a bill I co-authored with my colleague who sits on the Ways and
778 Means, Representative Jenkins, and supported by my colleague
779 here, Mr. Mullin, to incentivize the adoption of electronic health
780 records by behavioral health providers.

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781 While the Meaningful Use Program for Electronic Health
782 Records has not perfect, and we are still working to ensure
783 interoperability so that electronic health records actually talk
784 to each other, the program was successful in getting hospitals
785 and doctors to adopt electronic health records.

786 However, behavioral health providers were left out of this,
787 and many are still operating on paper records. Without
788 consistent electronic health records we will not be able to
789 achieve the integrated care systems and parity that we are
790 striving for. Data allows providers to notice trends in their
791 populations and more proactively reach out and create programs
792 to address them. Exchange of information across providers allows
793 them to coordinate care to better manage patients' multiple
794 chronic conditions.

795 We are also discussing ways to ensure that substance use
796 patient data can more easily be shared for the purposes of care
797 coordination. But even if privacy laws were changed, data would
798 not be properly shared without EHRs. I urge my colleagues to
799 support this bipartisan bill.

800 Thank you, and I yield back.

801 Mr. Burgess. The chair thanks the gentlelady. The
802 gentlelady yields back.

803 Are there other members seeking to be heard on H.R. 3331?

804 Seeing none, the question now occurs on forwarding H.R. 3331

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805 to the full committee.

806 All those in favor, say aye.

807 All those opposed, no.

808 The ayes appear to have it. The ayes have it, and the bill
809 is agreed to.

810 The chair now calls up committee print entitled "Welcome to
811 Medicare," Number 26, and asks the clerk to report.

812 [The information follows:]

813

814 ***** COMMITTEE INSERT 2 *****

815 Mr. Viau. Number 26 on the notice?

816 Mr. Burgess. Number 26 on the notice.

817 Mr. Viau. Discussion draft. To amend Title XVIII of the
818 Social Security Act to require a review of current opioid
819 prescriptions for chronic pain and screening for opioid use
820 disorder to be included in the Welcome to Medicare initial
821 preventative physical examination.

822 Mr. Burgess. Without objection, the first reading of the
823 bill is dispensed with and the bill is open for amendment at any
824 point.

825 So ordered.

826 Are there bipartisan amendments to the bill?

827 [No response.]

828 Mr. Burgess. Are there other amendments? Does any member
829 wish to speak on the bill for --

830 Mr. Bucshon. Mr. Chairman.

831 Mr. Burgess. The gentleman from Indiana seeks recognition.

832 Mr. Bucshon. Move to strike the last work.

833 Mr. Burgess. The gentleman is recognized for five minutes.

834 Mr. Bucshon. Mr. Chairman, according to HHS OIG, in 2016
835 one in three Medicare Part D beneficiaries received a prescription
836 opioid. And about 500,000 beneficiaries received high amounts
837 of opioids. It is with this in mind that I have draft legislation
838 that would update the Welcome to Medicare initial assessment to

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839 include a screening for patient opioid use for chronic pain.

840 The screening would review risk factors for abuse, provide
841 information on non-opioid alternatives for chronic pain
842 management and, if necessary, provide a referral to a specialist.
843 As a physician, I believe it is vital to support initiatives that
844 will help to prevent seniors from misusing or becoming addicted
845 to opioids while managing their chronic pain. Screening for
846 opioid use for chronic pain is an important step to help identify
847 those who may be at risk for dependence, and an opportunity to
848 educate patients on other effective but non-addictive options to
849 manage chronic pain and increase quality of life.

850 I urge my colleagues to support its draft and its common
851 sense.

852 And with that, I yield back the balance of my time.

853 Mr. Burgess. The chair thanks the gentleman. The
854 gentleman yields back.

855 Other members wishing to be heard on the committee print
856 Number 26?

857 Mr. Pallone. Yes.

858 Mr. Burgess. For what purpose does the gentleman from New
859 Jersey --

860 Mr. Pallone. Strike the last word, Mr. Chairman.

861 Mr. Burgess. The gentleman is recognized.

862 Mr. Pallone. I just want to take a moment to offer some

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863 thoughts on this bill. The version we are marking up today
864 represents a significant improvement from the version that was
865 noticed at the legislative hearing. The previous draft would
866 have added a pain assessment as part of this Welcome to Medicare
867 physical, as well as a referral to a pain specialist.

868 After the bill was posted I heard from numerous stakeholders
869 in the medical community that a similar approach adopted by the
870 joint commission in 2001 to treat pain as a fifth vital sign
871 actually contributed to the opioid epidemic. By requiring
872 healthcare providers to ask every patient about their pain and
873 incentivizing aggressive management of pain these measures may
874 have resulted in the over-prescribing of opioids. Thus, while
875 well intentioned, the previous draft of this bill could have
876 actually exacerbated our opioid epidemic.

877 I raised the concerns, these concerns at the legislative
878 hearing. And I thank the chairman and the bill's sponsors for
879 addressing them. The revised text replaces the previous pain
880 assessment as follows:

881 First, the provider conducts a review of the beneficiary's
882 opioid prescriptions;

883 Second, only those seniors with an opioid prescription then
884 receive a screening for opioid use disorder, a pain assessment,
885 information regarding non-opioid treatment options for chronic
886 pain management, and a referral to an appropriate specialist.

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887 This makes sense since seniors currently on opioids are at risk
888 for opioid abuse and are, in fact, more likely to have issues with
889 pain connected to the use of opioids.

890 And although appropriate layers have been added to ensure
891 that we do not push new patients onto unnecessary opioids, I still
892 fear there may be an unintended consequence of adding these
893 requirements to the statute. In an ideal world we would have been
894 at this point weeks ago, even before the legislative hearing. We
895 would have had a fully-informed and introduced bill that outside
896 stakeholders had enough, had seen enough in advance to warn of
897 us of the potential harmful effects of the initial draft. But,
898 instead, we are voting bills out of our subcommittee that have
899 not been appropriately vetted.

900 So, again, I appreciate that the majority listened to our
901 concerns on this particular bill and revised it in an attempt to
902 address those concerns, but I still fear this example belies
903 hidden troubles among the over 60 bills before us today. We are
904 dealing with a complex crisis in a haphazard and rushed manner.
905 Even well-intentioned bills could fuel further harm. And I look
906 forward to receiving stakeholder feedback and technical
907 assistance on this new draft. And I am hopeful we can get it to
908 a place where all of our members are comfortable with it before
909 the full committee markup.

910 And I yield back, Mr. Chairman.

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911 Mr. Burgess. Will the gentleman yield to the gentlelady
912 from California?

913 Mr. Pallone. Yes. If she likes, I yield to the gentlelady.

914 Ms. Eshoo. I thank the gentleman.

915 I have a question about part of the bill, a referral to a
916 specialist if deemed appropriate by the provider. To the makers
917 of the -- the authors of the bill, does that include something
918 other than pharmaceutical drugs?

919 There is another whole world in this, and that is the world
920 of biotechnology. And I don't know if it includes coverage for
921 inoculations, if it includes coverage for other products, for lack
922 of a better word. And has the bill been scored? How much does
923 this cost? I welcome the authors of the legislation addressing
924 that.

925 Mr. Bucshon. Will the gentlelady yield?

926 Ms. Eshoo. I would be happy to.

927 Mr. Bucshon. Yes. That I am aware of we don't have a score.

928 What I would say about appropriate referrals, from a
929 physician's perspective that would include, that could include
930 any, in my opinion, a referral to a person who has an expertise
931 in pain who also would be able to offer a multitude of possible
932 treatments for that condition, potentially even including
933 technology as you are talking about, not just opioid therapy.
934 Because in my experience, you know, in my practice for example,

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935 if I had a patient that had more than just post-surgical pain that
936 wasn't my area of expertise, so I always referred them to a pain
937 management person who then would make the broader decision about
938 what the appropriate therapy would be.

939 Ms. Eshoo. Thank you.

940 Mr. Pallone. Unless anyone else wants my time, Mr.
941 Chairman, I yield back.

942 Mr. Burgess. The chair thanks the gentleman. The
943 gentleman yields back.

944 Are there other members seeking time on the discussion draft?

945 [No response.]

946 Mr. Burgess. Seeing none, the question now occurs on
947 forwarding committee print as amend -- the committee print to the
948 full committee.

949 All those in favor, say aye.

950 All those opposed, say no.

951 The ayes appear to have it. The ayes have it. And
952 forwarding is agreed to.

953 The chair calls up committee print entitled Post-Surgical
954 Injections as an Opioid Alternative. This is Number 28 on this
955 report.

956 And the Chair asks the clerk to report.

957 [The information follows:]

958

959

***** COMMITTEE INSERT 3 *****

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960 Mr. Viau. Discussion draft. To amend Title XVIII of the
961 Social Security Act to provide for modifications in payment for
962 certain outpatient surgical services.

963 Mr. Burgess. Without objection, the first reading of the
964 bill is dispensed with. And the bill is open for amendment at
965 any point.

966 So ordered.

967 Are there bipartisan amendments to the bill?

968 [No response.]

969 Mr. Burgess. Are there members wishing to be heard on the
970 bill?

971 For what purpose does the gentleman from Illinois seek
972 recognition?

973 Mr. Shimkus. Strike the last word, Mr. Chairman.

974 Mr. Burgess. The gentleman is recognized for five minutes.

975 Mr. Shimkus. Thank you, Mr. Chairman.

976 I want to just briefly talk about the premise of this bill.
977 This is really is followed up from a letter that Dr. Bucshon signed
978 with our colleague from Chicago, Congressman Krishnamoorthi.
979 Most of us call him Raja. He talked to me on the floor of this.

980 This addresses two of the provisions. One of the ranking
981 member's four pillars was is the bill going to help us not create
982 addicts? And that is what this does.

983 And this follows up on my colleague from California,

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984 Congresswoman Eshoo, because if a pain doctor will not get
985 refunded for different types of technologies than just addiction,
986 then they are not going to do that. So this is an attempt to make
987 sure that there are other options for pain management that will
988 get funded. And that is the point.

989 So, we would rather have people get treated for pain without
990 addictive substances so they don't enter into the system. And
991 we want to make sure that they get paid for that.

992 Now, then the whole debate is the cost-benefit analysis. A
993 little bit of additional cost to get them treated with
994 non-addictive pain medicine, is that worth the price to pay so
995 that people don't have the risk of addiction? And I think it is.
996 I think Dr. Bucshon in his letter, with a lot of members of this
997 subcommittee, and then also with Raja, agree. And that is why
998 we are putting forth this provision in this bill.

999 I talked with Raja last night. He hopes that I would plead
1000 and beg my colleagues on the other side to look at it positively.
1001 So, you can tell him I did that in the subcommittee mark.

1002 And with that I will -- does the ranking, do you want your
1003 full time? Do you want my time?

1004 Mr. Pallone. I think I will take my own time.

1005 Mr. Shimkus. Okay. I yield back.

1006 Mr. Burgess. The chair thanks the gentleman. The
1007 gentleman yields back.

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1008 Other members seeking time on the committee print? The
1009 gentleman from New Jersey is recognized for five minutes.

1010 Mr. Pallone. Thank you, Mr. Chairman.

1011 And I appreciate the gentleman from Illinois talking about
1012 my test. I guess he was talking about my test. But I don't think
1013 this meets the test. That is the problem, Mr. Shimkus, in my
1014 opinion.

1015 I did mention that I would evaluate the bills in this
1016 committee today based on two principles: whether the proposal will
1017 meaningful improve access to treatment for opioid use disorders;
1018 or whether the proposal will help to prevent people from getting
1019 addicted to opioids in the first place. And I don't think the
1020 bill at this point meets that test.

1021 This is not an opioid, in my opinion. It is a bill to address
1022 the reimbursement issue for physicians that administer certain
1023 injections at ambulatory surgical centers. And the idea that
1024 increasing reimbursement for these particular codes will have a
1025 meaningful impact on the opioid epidemic I think is a stretch.
1026 I have seen no evidence that increasing reimbursement for these
1027 six codes and only in the ambulatory surgical center setting will
1028 lead to a decreased opioid prescribing or a decreased prevalence
1029 of addiction. And I fail to understand why we are privileging
1030 these therapies over others and picking winners as part of this
1031 opioid process.

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1032 Why are we only addressing reimbursement at ASCs and not
1033 hospital outpatient departments? But the worse thing is, are we
1034 really going to fix reimbursements at 2016 rates indefinitely?
1035 CMS does routine maintenance of the payment systems that pays ASCs
1036 and hospital outpatient departments in order to account for new
1037 technologies and shifts in relative value. How does it make sense
1038 to set reimbursement rates permanently in statute at 2016 levels?
1039 I don't know that we have ever done that. It almost, it almost
1040 smacks of the CRA procedure which is that, you know, once you visit
1041 this you can never revisit it again.

1042 And I don't think we should be putting CMS in that kind of
1043 a straightjacket. So that is my major concern with this, Mr.
1044 Chairman.

1045 But this bill is also, as Mr. Shimkus said, is going to cost
1046 money and we don't know how much since CBO has not yet provided
1047 an analysis. Fundamentally, my question to my colleagues is, is
1048 this a good use of scarce resources in the midst of an opioid
1049 epidemic when less than one in five Americans with opioid use
1050 disorders receive treatment for this chronic disease.

1051 So at this point I cannot support this bill. And I would
1052 urge my colleague to vote against it.

1053 I don't know if somebody wants my time or just wants to take
1054 --

1055 Mr. Green. Would the gentleman yield?

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1056 Mr. Pallone. I yield to Mr. Green.

1057 Mr. Green. Thank you for yielding to me.

1058 And, again, this is a draft that we haven't had direct
1059 testimony on as much as I can remember. The majority's argument
1060 that these non-opioid alternatives for back pain could prevent
1061 some patients from getting opioids because they could receive
1062 injections rather than opioids. However, there is no evidence
1063 increasing the reimbursement for these particular codes would
1064 reduce opioid prescribing. Moreover, the interventions are of
1065 questionable value in improving patient outcomes. There is
1066 little or no evidence showing the efficacy of these injections
1067 in treating pain.

1068 Mr. Chairman, I would hope that if this passes you will sit
1069 down with us between now and the full committee. For example,
1070 we could do a 2-year freeze of payment rates instead of
1071 indefinitely, and maybe get more information on it.

1072 And I will yield back my time to my ranking member.

1073 Mr. Pallone. I don't know if anybody else wants my -- you
1074 want my time? Yes, I yield to the gentlewoman from California.

1075 Ms. Eshoo. Well, I think the questions keep raising
1076 questions. I think the basic premise of the legislation is good.
1077 How are we going to change this if we don't change it, change the
1078 statutes? I don't, I mean I am posing a sincere question here.

1079 Look, if doctors are sending people home from surgery with

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1080 60 and 100 tablets of OxyContin after a hip replacement, which
1081 is the second most common surgery in the country, we have got a
1082 problem. We really have a problem. So I think that this
1083 legislation is, as I understand it, is directed to move away from
1084 that.

1085 But what the ranking member just said, how do we implement
1086 that without changing the statute? I am asking you a question.

1087 Mr. Pallone. Well, I think the biggest concern I have is
1088 the fact that the way this bill is written -- and that is why I
1089 really wish that we weren't moving this bill today -- the way it
1090 is written it basically sets the reimbursement rate indefinitely.
1091 In other words, it says that the 2016 reimbursement rate is the
1092 rate that we were going to use, and we can't change it again.

1093 Now, of course you could always argue that another Congress
1094 could come back and change it. But CMS wouldn't be able to. So,
1095 essentially what we are doing here is saying that we are going
1096 to set the rate at 2016, and we are not going to let CMS change
1097 it again.

1098 I just don't know, regardless of the underlying substance
1099 of the bill, I don't know that we have ever done that. And I don't
1100 think we should. I don't like the idea of telling CMS we are
1101 setting this rate indefinitely at the 2016 level and you can't
1102 change it again.

1103 Ms. Eshoo. Well, let me just reclaim my time.

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1104 What does Mr. Shimkus think? I mean, do you think that there
1105 is more work to do with the --

1106 Mr. Shimkus. Well, yes. I mean, --

1107 Ms. Eshoo. -- reimbursement?

1108 Mr. Shimkus. -- we are a subcommittee. We have got a full
1109 committee mark. We can address these things.

1110 Ms. Eshoo. All right.

1111 Mr. Shimkus. One thing I didn't mention was data
1112 collection. Part of this is collecting the data to make sure that
1113 the actual services that we are rendering are for pain management
1114 to try to address that, that issue of are they helpful or are they
1115 not helpful. And so the data collection is a provision.

1116 There was also something raised about hospitals. We just
1117 don't have the data on hospitals. We have the data on ambulatory
1118 service centers.

1119 So, I am happy to look at ways we can do it, and if we can
1120 move this forward and keep talking.

1121 Mr. Pallone. Mr. Chairman, could we ask for an additional
1122 minute just to have a little dialog on this a minute or two?

1123 Mr. Burgess. The chair is prepared to yield to the gentleman
1124 from Indiana, at which time I will yield to Mr. Green who can yield
1125 to you.

1126 Mr. Pallone. Sure. Sure.

1127 Mr. Burgess. The chair recognizes the gentleman from

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1128 Indiana for five minutes.

1129 Mr. Bucshon. Yes. I move to strike the last word.

1130 I just want to comment in general on pain blocks and other
1131 non-opioid injections like long-acting non-steroidals and other
1132 things. In the immediate post-operative period if you can get
1133 ahead of people's pain with either a pre-operative right before
1134 the surgery or a post-operative pain block or an injection of a
1135 non-opioid alternative, then the likelihood of ever requiring an
1136 opioid at all post-surgically drops dramatically.

1137 And in that respect, if it is not being reimbursed properly
1138 then you will -- these things won't happen. And so that is just
1139 a general comment.

1140 And I think this would potentially move us in the right
1141 direction.

1142 Mr. Pallone. Mr. Chairman, --

1143 Mr. Bucshon. Yes.

1144 Mr. Pallone. -- could I ask that the gentleman yield?

1145 Mr. Bucshon. I yield, yes.

1146 Mr. Pallone. My recollection is to the extent that we deal
1147 with reimbursement rates and we try to correct it, we certainly
1148 have situations where a reimbursement rate is supposed to be cut,
1149 and we have said let's postpone that cut for a year or two while
1150 we study it and see whether that makes sense. We have done that.

1151 The problem here, though, is I think at least threefold,

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1152 which is, first of all, the reimbursement rate was cut, so we would
1153 be restoring it.

1154 But beyond that, I haven't seen any evidence that says
1155 definitively that if you go back to this old 2016 reimbursement
1156 rate that this is going to make a difference in terms of the opioid
1157 crisis. So one thing that could be done is to provide the
1158 committee with that information.

1159 But beyond that, the biggest concern is I don't ever remember
1160 a case where we say, okay, we are going to go back to a 2016
1161 reimbursement rate and that is going to be set indefinitely by
1162 statute and CMS is not going to have the ability to change it.
1163 I mean, that to me makes -- I mean I don't want to be, you know,
1164 nasty about it, but that to me makes no sense. I mean, you know,
1165 CMS has to decide in a given year what is the priority, how much
1166 they want to spend on things. There is only so much money out
1167 there.

1168 And to say we are going to establish this rate at 2016, and
1169 you can't change it, I -- there is no precedent for that. And
1170 I don't think it is wise. And that is my concern.

1171 Mr. Bucshon. Yes, reclaiming my time. Anybody else want
1172 time?

1173 Mr. Shimkus. If the gentleman would yield.

1174 Mr. Bucshon. Mr. Shimkus, yield to Mr. Shimkus.

1175 Mr. Shimkus. Just, yes, and I will try and just say, again,

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1176 this is a response to a letter that was sent by my colleague and
1177 the like. The point being there is a data collection issue. And
1178 in our discussions we could say, well, let's, let's do this, let's
1179 collect the data, let's revisit.

1180 Mr. Pallone. Well, I understand that. But that is not what
1181 you are saying. You are saying --

1182 Mr. Shimkus. Well, I am saying that now.

1183 Mr. Pallone. Well, if that is the case then why don't we
1184 hold the bill and we will talk about it more? Why are we moving
1185 --

1186 Mr. Shimkus. Well, I think we need to -- and I guess if we
1187 believe this crisis is real, which we all do, and we need, we can
1188 move forward. We can always decide not to move it to the full
1189 committee.

1190 Mr. Pallone. Well, I understand that.

1191 Mr. Shimkus. Or we can decide that it doesn't go to the
1192 floor. It still has to deal with the Senate. I mean, there is
1193 a lot of places for this to get adjusted. It doesn't have to be
1194 perfect out of a subcommittee.

1195 Mr. Bucshon. Reclaiming my time. Yes, I yield.

1196 Ms. Eshoo. Thank you. I thank the gentleman.

1197 I am interested in the operating principle of this bill. I
1198 think it is an important one. Because I think that any door that
1199 is easily opened to the use of opioids, we have to shut that door

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1200 and go another way because people are becoming addicted. And I
1201 think that the base bill addresses itself to that.

1202 But I do think on the money side, Mr. Shimkus and others,
1203 that there is some work to be done. I am not one of the authors
1204 of this and but I would be happy to work with you. I think there
1205 is some work to be done. But it is worth working on because of
1206 the things that we are talking about. And I think that it would
1207 be a march to folly if we dropped the whole thing. But I also
1208 think the bill needs some work.

1209 So I will work with you on it. And I wanted, I just wanted
1210 to speak to that.

1211 I thank the gentleman for yielding to me.

1212 Mr. Bucshon. I yield back, Mr. Chairman.

1213 Mr. Burgess. The chair thanks the gentleman. The
1214 gentleman yields back.

1215 What purpose is the gentleman from Texas seeking
1216 recognition?

1217 Mr. Green. Strike the last word.

1218 Mr. Burgess. The gentleman is recognized for five minutes.

1219 Mr. Green. Mr. Chairman, I understand where we are going
1220 with this and but I don't think it has been ripe enough to deal
1221 with it. That is why I said earlier. And if Mr. Shimkus and Mr.
1222 Bucshon, because I know there is another piece of legislation that
1223 we have, another draft that Congressman Bucshon and Peters has

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1224 incentivizing non-opioid drugs that we might be able to work on,
1225 too, that if we could -- do you have a timetable? Are you going
1226 to rush this through markup in the full committee? The chair is
1227 not here, but we will have a --

1228 Mr. Burgess. Will the gentleman yield?

1229 Mr. Green. I will be glad to yield.

1230 Mr. Burgess. The gentleman understands that we do feel that
1231 it is important to work with some dispatch. But at the same time,
1232 we want to be certain that any problems are completely resolved.
1233 The full committee markup is not likely to happen for several
1234 weeks. More activity is going to be several weeks beyond that.

1235 So I think I can assure the gentleman there will be ample
1236 time to work on some of the finer points which are causing concern.

1237 Mr. Green. Reclaiming my time, and I know we are all
1238 perfections on the Energy and Commerce Committee, so if we could
1239 have a few weeks there to perfect this and sit down and work
1240 together with our staff. I know next week we are out of session
1241 and that will give time, too. So, but --

1242 Mr. Pallone. Will the gentleman yield?

1243 Mr. Green. I yield.

1244 Mr. Pallone. I just feel strongly, though, that this bill
1245 the way it is set now with this indefinite status for the setting
1246 the reimbursement rate is not acceptable. So I am going to ask
1247 that we have a roll call on it, Mr. Chairman.

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1248 Mr. Green. Well, you have that right. I was hoping we could
1249 fix it because we are not ready today to do it because we have
1250 so many other bills.

1251 I yield back my time.

1252 Mr. Burgess. Are there other members that wish to be heard
1253 on the bill?

1254 [No response.]

1255 Mr. Burgess. Seeing none, the question then occurs on
1256 reporting the bill, the committee print to the full committee.

1257 All those in favor, say aye.

1258 All those opposed, say no.

1259 A roll call vote has been requested. The clerk will call
1260 the roll.

1261 The Clerk. Mr. Guthrie?

1262 Mr. Guthrie. Aye.

1263 The Clerk. Mr. Guthrie votes aye.

1264 Mr. Barton?

1265 [No response.]

1266 The Clerk. Mr. Upton?

1267 Mr. Upton. Aye.

1268 The Clerk. Mr. Upton votes aye.

1269 Mr. Shimkus?

1270 Mr. Shimkus. Aye.

1271 The Clerk. Mr. Shimkus votes aye.

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1272 Mrs. Blackburn?
1273 [No response.]
1274 The Clerk. Mr. Latta?
1275 [No response.]
1276 The Clerk. Mrs. McMorris Rodgers?
1277 [No response.]
1278 The Clerk. Mr. Lance.
1279 Mr. Lance. Aye.
1280 The Clerk. Mr. Lance votes aye.
1281 Mr. Griffith?
1282 Mr. Griffith. Aye.
1283 The Clerk. Mr. Griffith votes aye.
1284 Mr. Bilirakis?
1285 Mr. Bilirakis. Aye.
1286 The Clerk. Mr. Bilirakis votes aye.
1287 Mr. Long?
1288 Mr. Long. Aye.
1289 The Clerk. Mr. Long votes aye.
1290 Mr. Bucshon?
1291 Mr. Bucshon. Aye.
1292 The Clerk. Mr. Bucshon votes aye.
1293 Mrs. Brooks.
1294 Mrs. Brooks. Aye.
1295 The Clerk. Mrs. Brooks votes aye.

1296 Mr. Mullin?
1297 Mr. Mullin. Aye.
1298 The Clerk. Mr. Mullin votes aye.
1299 Mr. Hudson?
1300 Mr. Hudson. Aye.
1301 The Clerk. Mr. Hudson votes aye.
1302 Mr. Collins?
1303 Mr. Collins. Aye.
1304 The Clerk. Mr. Collins votes aye.
1305 Mr. Carter?
1306 Mr. Carter. Aye.
1307 The Clerk. Mr. Carter votes aye.
1308 Chairman Walden?
1309 The Chairman. Aye.
1310 The Clerk. Chairman Walden votes aye.
1311 Mr. Green?
1312 Mr. Green. No.
1313 The Clerk. Mr. Green votes no.
1314 Mr. Engel?
1315 [No response.]
1316 The Clerk. Ms. Schakowsky?
1317 Ms. Schakowsky. No.
1318 The Clerk. Ms. Schakowsky votes no.
1319 Mr. Butterfield?

1320 [No response.]

1321 The Clerk. Ms. Matsui?

1322 Ms. Matsui. No.

1323 The Clerk. Ms. Matsui votes no.

1324 Ms. Castor?

1325 Ms. Castor. No.

1326 The Clerk. Ms. Castor votes no.

1327 Mr. Sarbanes?

1328 [No response.]

1329 The Clerk. Mr. Lujan?

1330 [No response.]

1331 The Clerk. Mr. Schrader?

1332 [No response.]

1333 The Clerk. Mr. Kennedy?

1334 Mr. Kennedy. No.

1335 The Clerk. Mr. Kennedy votes no.

1336 Mr. Cardenas?

1337 [No response.]

1338 The Clerk. Ms. Eshoo?

1339 Ms. Eshoo. Pass.

1340 The Clerk. Ms. Eshoo passes.

1341 Ms. DeGette?

1342 Ms. DeGette. No.

1343 The Clerk. Ms. DeGette votes no.

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1344 Mr. Pallone?

1345 Mr. Pallone. No.

1346 The Clerk. Mr. Pallone votes no.

1347 Chairman Burgess?

1348 Mr. Burgess. Aye.

1349 The Clerk. Chairman Burgess votes aye.

1350 Mr. Burgess. Are there any other members wishing to be

1351 recorded?

1352 The Clerk. Mr. Lujan?

1353 Mr. Lujan. No.

1354 The Clerk. Mr. Lujan votes no.

1355 Mr. Burgess. How is the gentleman from New York recorded?

1356 The Clerk. Mr. Engel is not recorded.

1357 Mr. Engel. No.

1358 The Clerk. Mr. Engel votes no.

1359 Mr. Butterfield?

1360 Mr. Butterfield. No.

1361 The Clerk. Mr. Butterfield votes no.

1362 Mr. Burgess. How is Mr. Latta recorded?

1363 The Clerk. Mr. Latta is not recorded.

1364 Mr. Latta. Aye.

1365 The Clerk. Mr. Latta votes aye.

1366 Mr. Burgess. And how is Mr. Barton recorded?

1367 The Clerk. Mr. Barton is not recorded.

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1368 Mr. Barton. Yes.

1369 The Clerk. Mr. Barton votes aye.

1370 Mr. Burgess. The gentleman from Massachusetts has been
1371 recorded once. It will not be necessary to --

1372 The Clerk. Mr. Kennedy votes no.

1373 Mr. Green. You are out of order. You are not from Chicago.

1374 [Laughter.]

1375 Mr. Burgess. The clerk will report.

1376 The Clerk. Mr. Chairman, on that vote there were 17 ayes
1377 and 10 nays.

1378 Mr. Burgess. Seventeen ayes and 10 nays, the committee
1379 print is adopted or referred to the committee.

1380 The chair calls up committee print entitled Alternative
1381 Payment Model for Treating Substance Use Disorder. This is
1382 Number 29 on the provided list. The chair asks the clerk to
1383 report.

1384 [The information follows:]

1385

1386 ***** COMMITTEE INSERT 4 *****

1387 The Clerk. Discussion draft. To amend Title XIX of the
1388 Social Security Act to provide for opioid use disorder treatment
1389 demonstration program.

1390 Mr. Burgess. Without objection, the first reading of the
1391 bill is dispensed with. And the bill is open for amendment at
1392 any point.

1393 So ordered.

1394 There are bipartisan amendments on the bill.

1395 [No response.]

1396 Mr. Burgess. Does any member wish to be heard on the bill?

1397 For what purpose does the gentleman from New Jersey seek
1398 recognition?

1399 Mr. Pallone. Strike the last word, Mr. Chairman, in support
1400 of the bill.

1401 Mr. Burgess. The gentleman is recognized for five minutes.

1402 Mr. Pallone. I just wanted to express my support for this
1403 legislation introduced by Congressman Ruiz. The bill is critical
1404 to a comprehensive approach to all those affected by this
1405 epidemic.

1406 Medicare beneficiaries are vulnerable to systematic opioid
1407 over-prescribing. The Department of Health and Human Services
1408 Office of Inspector General estimates that over half a million
1409 individuals in Medicare Part D received high amounts of opioids
1410 in 2016, with the average dose far exceeding the manufacturer's

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1411 recommended amount.

1412 Opioid use among older adults is high and growing.

1413 According to SAMHSA, the population of older adults who misuse

1414 prescription opioids is projected to double from 2004 to 2020.

1415 Despite this growing issue, there are significant gaps in the

1416 traditional Medicare benefit. And far too few of our nation's

1417 seniors and disabled populations are able to access comprehensive

1418 evidence-based treatment for opioid addictions.

1419 The Advancing High Quality Treatment for Opioid Use

1420 Disorders in Medicare Act introduced by Representative Ruiz

1421 provides an opportunity to both expand access to care, as well

1422 as to transform how our healthcare system delivers treatment for

1423 opioid addiction. The bill would create a demonstration for an

1424 alternative payment model for treating opioid use disorders in

1425 Medicare. The model would reward coordinated care teams that

1426 provide high quality evidence-based medication-assisted

1427 treatment in conjunction with the appropriate psychosocial

1428 services.

1429 We hope this bill will fill the treatment gap that Medicare

1430 beneficiaries face, especially in terms of appropriate

1431 psychosocial services for which there may be currently limited

1432 incentive to provide.

1433 But the bill goes beyond the Medicare program. It pushes

1434 the Medicare program to innovate and pay opioid treatment

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1435 providers for value by providing incentive payments for
1436 performance. This has the potential to drive transformation
1437 throughout the healthcare system. As we all know, Medicare is
1438 the 800-pound gorilla in our healthcare system. When Medicare
1439 pays for something, private payers take notice. When Medicare
1440 stagnates and fails to innovate, private payers similarly face
1441 inertia. When Medicare innovates and pushes the bounds, there
1442 is a potential to have broader transformative effects on the
1443 healthcare system.

1444 In the Medicare program there are currently no quality
1445 measures that measure success in treating opioid use disorders.
1446 We have many measures in opioid prescribing, but nothing dealing
1447 with the quality of care that Medicare beneficiaries receive for
1448 opioid use disorders. We have nothing approaching value-based
1449 care for opioid use disorders or substance use disorders more
1450 broadly. And this is true for Medicare, but also largely true
1451 for the private sector. And this needs to change.

1452 And that is why I commend Representative Ruiz for his work
1453 on this initiative. And urge my colleagues to support this bill.
1454 Passage and successful implementation of this legislation could
1455 have far-reaching effects for our healthcare system, as well as
1456 for our Medicare beneficiaries suffering from the chronic relapse
1457 and disease of opioid addiction.

1458 And unless someone else wants the time, I yield back, Mr.

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1459 Chairman. Oh, I yield to Mr. Green.

1460 Mr. Green. Mr. Chairman, I also want to support this piece
1461 of legislation. Dr. Ruiz is a member of our committee and also
1462 an emergency doctor. And I value our physicians on our committee
1463 and their expertise. And I think this is a -- this piece of
1464 legislation to look at another model for treating substance abuse
1465 is something that is not mandatory, but we create a demonstration
1466 project.

1467 And I yield back.

1468 Mr. Pallone. And I yield back, Mr. Chairman.

1469 Mr. Burgess. The chair thanks the gentleman. The
1470 gentleman yields back.

1471 For what purpose does the gentleman from Oregon seek
1472 recognition?

1473 The Chairman. Thank you, Mr. Chairman. I, too, support
1474 this legislation. And I appreciate Dr. Ruiz bringing it to our
1475 attention.

1476 Just as a matter of discussion, it is a discussion draft not
1477 a bill. It is one of these good ideas, though, that is appropriate
1478 before the subcommittee today. And, again, showing bipartisan
1479 support for us trying to tackle this deadly issue we face in the
1480 country.

1481 And with that, I would yield the balance of my time to the
1482 gentleman from Indiana, Dr. Bucshon.

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1483 Mr. Bucshon. Thank you for yielding.

1484 I want to say at the state at the start that I do support
1485 the development of APMs. Moving to value-based,
1486 patient-centered, risk-bearing care is essential for the
1487 continued improvement of the Medicare program.

1488 I also want to mention that the language has improved
1489 substantially since the original iterations of the bill.

1490 Why there might be absolute -- why there might absolutely
1491 be a space to develop an APM for substance abuse disorder, I want
1492 to make sure that we are doing it right and have the appropriate
1493 size and scope. So further feedback from CBO and CMS is
1494 essential.

1495 That said, I do want to flag an important tie-in with
1496 information sharing in 42 CFR Part 2 that I believe if it is not
1497 addressed would cripple such efforts. For current models like
1498 ACOs, CMS provides claims data to understand the risk present in
1499 the community. However, CMS scrubs out any data related to Part
1500 2 or non-related healthcare condition that was submitted on a
1501 claims form with a Part 2 incident.

1502 Currently, on the average 4.5 percent of Medicare data is
1503 scrubbed and 8 percent of Medicaid data is scrubbed.
1504 Essentially, current models are being forced to take on financial
1505 risk for a patient population they cannot coordinate care for,
1506 unlike every other disease that is covered under HIPAA, including

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1507 HIV/AIDS, hepatitis C, and STDs.

1508 In order for payment models to work the way they are intended,
1509 they need to access -- they need access to all of the data on
1510 patients they are taking risks for in order to address the complete
1511 needs of patients, as well as all of the conditions they may be
1512 facing. If we move forward with the bill, I feel it is an issue
1513 that we need to address. We want to work together to get this
1514 bill to an area where we can advance it to the full committee and
1515 down the field.

1516 I yield.

1517 Mr. Burgess. The chair thanks the gentleman. The
1518 gentleman yields back.

1519 Are there other members wishing to be heard on the discussion
1520 draft?

1521 [No response.]

1522 Mr. Burgess. If not, the question now occurs on forwarding
1523 the committee print to the full committee.

1524 All those in favor, say aye.

1525 Those opposed, no.

1526 The ayes appear to have it. The ayes have it. And the print
1527 is agreed to be forwarded.

1528 The chair calls up committee print entitled Use of Telehealth
1529 to Treat Opioid Use Disorder, Number 30 on the discussion draft
1530 list. And ask the clerk to report.

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1531

[The information follows:]

1532

1533

***** COMMITTEE INSERT 5 *****

1534 The Clerk. Discussion draft. To amend Title XVIII of the
1535 Social Security Act to provide the Secretary of Health and Human
1536 Services authority to waive certain Medicare telehealth
1537 requirements in the case of certain treatment of an opioid use
1538 disorder or co-occurring mental health disorder.

1539 Mr. Burgess. Without objection, the first reading of the
1540 bill is dispensed with and the bill is open for amendment at any
1541 point. So ordered.

1542 Are there bipartisan amendments to the bill?

1543 [No response.]

1544 Mr. Burgess. Are there members that wish to be heard on the
1545 bill?

1546 Ms. Matsui. Mr. Chairman.

1547 Mr. Burgess. For what purpose does the gentlelady from
1548 California seek recognition?

1549 Ms. Matsui. I move to strike the last word.

1550 Mr. Burgess. The gentlelady is recognized for five minutes.

1551 Ms. Matsui. Mr. Chairman, I would like to speak in support
1552 of H.R. 5603, the Access to Telehealth Services for Opioid Use
1553 Disorders Act, which was a discussion draft at one of our recent
1554 opioid hearings and which I introduced as a bill yesterday with
1555 my colleague on the committee, Representative Cardenas.

1556 There are great things happening around the country with
1557 telehealth. Academic medical centers like U.S. Davis in my

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1558 district, insurance companies, medical device companies,
1559 clinics, and others are all finding creative ways to use
1560 technology to get more evidence-based care to patients faster and
1561 more conveniently. Patients can now work with their clinicians
1562 to monitor their blood sugar in real time and notice issues before
1563 they become emergencies.

1564 Patients can see a doctor on an app on their phone for minor
1565 conditions without taking time off of work to travel to an office.
1566 However, despite all the success we have seen with these types
1567 of programs, Medicare has lagged behind in encouraging them.
1568 That is why I have worked with my colleagues on this committee,
1569 including Congressman Bill Johnson to work to expand access to
1570 telemedicine and Medicare and Medicare Advantage.

1571 Our bill, H.R. 3482, the Evidence-Based Telehealth Expansion
1572 Act, would allow the Secretary of HHS to waive current
1573 restrictions on telehealth in Medicare such as the requirement
1574 that a patient be at a specific type of rural site. Telehealth
1575 is not only used for rural areas but urban and suburban areas as
1576 well.

1577 The bill before us today, H.R. 5603, is based on my
1578 legislation with Congressman Johnson but tailored specifically
1579 to open up reimbursement for telehealth for substance use services
1580 for people with opioid use disorders. While I would prefer to
1581 open reimbursement for telemedicine for a variety of

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1582 evidence-based services, I think this is an important first step
1583 that will get more services to people suffering from opioid
1584 addiction now, and can be used as a model that would translate
1585 to other services in the future.

1586 I urge my colleagues to support this bill. And I also would
1587 like to submit two letters of support for the record. The first
1588 is from the National Associations of Licensing Boards for Doctors,
1589 Nurses, and Pharmacists. The second is from the Healthcare
1590 Information and Management Systems Society and the Personal
1591 Connected Health Alliance.

1592 [The information follows:]

1593

1594 ***** COMMITTEE INSERT 6 *****

1595 Ms. Matsui. Thank you, Mr. Chairman. I yield back.

1596 Mr. Pallone. Could I ask the gentlewoman to yield?

1597 Ms. Matsui. Yes. I yield to the gentleman.

1598 Mr. Pallone. I just wanted to express my support for her
1599 bill. I commend her for the work on this important bill.

1600 When used appropriately, telehealth technology can be an
1601 effective and lower-cost method for expanding services to
1602 underserved areas. And I don't think we can afford to not use
1603 the full potential of technology to connect folks struggling with
1604 opioid addictions to an already limited behavioral health
1605 workforce. We hope this bill will be one of many steps towards
1606 reducing the human cost of this opioid crisis.

1607 The legislation before us expands access to telehealth
1608 services for Medicare beneficiaries with opioid use disorders by
1609 giving the Secretary the authority to lift the rural and
1610 originating site requirements for the treatment of opioid use
1611 disorders and co-occurring mental health disorders. So,
1612 effectively, the bill will expand the ability for people to
1613 receive the essential counseling services they need to find and
1614 maintain recovery without the need to drive hundreds of miles or
1615 forego care entirely.

1616 So I yield back to the gentlewoman.

1617 Ms. Matsui. I yield back.

1618 Mr. Burgess. The chair thanks the gentlelady. The

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1619 gentlelady yields back.

1620 Are there other members seeking to be heard on the bill? For
1621 what purpose does the gentleman from Kentucky seek recognition?

1622 Mr. Guthrie. Strike the last word.

1623 Mr. Burgess. The gentleman is recognized for five minutes.

1624 Mr. Guthrie. Thank you, Mr. Chairman.

1625 We support utilizing telehealth services to help patients.
1626 And we appreciate the effort of minimizing the CBO costs. But
1627 we still must keep in mind the full costs to be good stewards of
1628 the taxpayers' dollars. Conversely, if the actuary cannot
1629 certify the conditions under the bill, we have not provided a
1630 benefit to any beneficiary.

1631 Also, without aligning Part 2 with HIPAA about how we can
1632 provide -- how a provider can completely oversee a patient
1633 remotely if they can't see the complete medical record.

1634 All that said, I am willing to continue this conversation.
1635 And we want to work together and move as we move into the full
1636 committee.

1637 I yield back.

1638 Mr. Burgess. The chair thanks the gentleman. The
1639 gentleman yields back.

1640 Other members wishing to be heard on Discussion Draft Number
1641 30?

1642 [No response.]

1643 Mr. Burgess. Seeing none, the question now occurs on
1644 forwarding the committee print to the full committee.

1645 All those in favor, say aye.

1646 All those opposed, no.

1647 The ayes appear to have it. The ayes have it. And the bill
1648 is agreed to and forwarded to the full committee.

1649 The chair now calls up the committee print entitled
1650 Incentivizing Non-Opioid Drugs, Number 31 on the discussion draft
1651 list. I would ask the clerk to report.

1652 [The information follows:]

1653

1654 ***** COMMITTEE INSERT 7 *****

1655 The Clerk. Discussion draft. To amend Title XVIII of the
1656 Social Security Act to encourage the use of non-opioid analgesics
1657 for the management of post-surgical pain under the Medicare
1658 program, and for other purposes.

1659 Mr. Burgess. Without objection, the first reading of the
1660 bill is dispensed with and the bill is open for amendment at any
1661 point. So ordered.

1662 Are there bipartisan amendments to the bill?

1663 [No response.]

1664 Mr. Burgess. Are there members wishing to be heard on the
1665 bill?

1666 For what purpose does the gentleman from Indiana seek
1667 recognition?

1668 Mr. Bucshon. Mr. Chairman, I move to strike the last word.

1669 Mr. Burgess. The gentleman is recognized for five minutes.

1670 Mr. Bucshon. We have heard testimony before this committee
1671 about the need for new and innovative non-opioid therapies for
1672 post-surgical pain relief. This draft legislation, co-sponsored
1673 also by my colleague Scott Peters as well as myself, addresses
1674 the lack of alternatives to opioids for post-surgical pain.

1675 It would provide for a temporary pass-through payment for
1676 non-opioid analgesics used during surgical procedures. As a
1677 physician, I know the importance of being able to properly manage
1678 a patient's pain after surgery. And physicians need additional

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1679 effective options that don't come with a serious risk of
1680 dependence.

1681 This bipartisan draft legislation will help prevent
1682 addiction by incentivizing the development and use of non-opioid
1683 pain alternatives for post-surgical pain. I am committed to
1684 continuing to work in a strong bipartisan manner with Congressman
1685 Peters to get this policy right before it is formally introduced.
1686 This draft legislation is supported by the Abuse Deterrent
1687 Coalition, American Society of Anaesthesiologists, and the
1688 American Society of Interventional Pain Physicians.

1689 I ask my colleagues to support Congressman Peters and myself
1690 in this important effort. And I yield back.

1691 Mr. Burgess. Will the gentleman yield?

1692 Mr. Bucshon. I yield to the chairman.

1693 Mr. Burgess. I thank the gentleman for yielding.

1694 In our panel that we had last Thursday, although it wasn't
1695 a hearing it was open to any member of the committee who wished
1696 to attend, we heard from the representative from Shatterproof.
1697 And he actually talked about this problem and the relative lack
1698 of alternatives that exist. And it was his feeling that research
1699 has in fact been funded but it has been slow to be taken up.

1700 So I appreciate the gentleman bringing this forward. I
1701 think it's an important concept that needs to be. If it needs
1702 additional work, then so be it. But it is well worth our including

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1703 it in this panel of bills.

1704 And I will yield back to the gentleman from Indiana.

1705 Mr. Bucshon. And I yield back.

1706 Mr. Burgess. The gentleman yields back.

1707 Other members wishing to be heard on the bill? For what
1708 purpose does the gentleman from New Jersey seek recognition?

1709 Mr. Pallone. Strike the last word in opposition to the bill.

1710 Mr. Burgess. The gentleman is recognized for five minutes.

1711 Mr. Pallone. Mr. Chairman, I feel strongly that the bills
1712 we should be considering as part of this process provide treatment
1713 for opioid use disorders or prevent addiction from occurring in
1714 the first place. And this bill does not meet that test.

1715 This bill appears to be designed specifically to financially
1716 benefit one drug company which has several non-opioid analgesic
1717 products in the pipeline. I can list dozens of low cost, generic,
1718 non-opiate analgesics that are used to treat post-operative pain
1719 that are already on the market. And it is unclear that this
1720 particular drug manufactured by this particular company has any
1721 significant added benefits on top of the existing drugs and
1722 therapies. And yet, we are planning to legislate spending
1723 hundreds or potentially thousands of dollars per dose for this
1724 drug in addition to the already considerable reimbursement that
1725 this drug will get on three years of pass-through status.

1726 This is picking winners and losers amongst different

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1727 therapies. And this is not something Congress should be doing,
1728 should be in the business of doing, nor has the expertise to even
1729 attempt.

1730 Additionally, new drugs already get three years of
1731 pass-through in the OPPS. I have heard no evidence to establish
1732 that an additional two years of pass-through status is necessary
1733 to incentivize the development of new non-opioid analgesics.

1734 Moreover, I am deeply troubled by the precedent set by this
1735 bill. What will prevent other drug companies from coming in and
1736 demanding an additional two years of pass-through status. How
1737 should Congress make principled decisions amongst all of the
1738 competing drug therapies? In addition, how will this bill and
1739 future bills that seek to extend pass-through treatment for new
1740 drugs impact drug spending and out-of-pocket costs for
1741 beneficiaries when we know we are already struggling with the high
1742 cost of drugs?

1743 Now, as you know, both President Trump and many others on
1744 both sides of the aisle have talked about the high cost of
1745 prescription drugs. I am very concerned about this in that
1746 respect. I don't think this is how we should legislate. And this
1747 is not how we should use scarce resources during a public health
1748 crisis. And so I urge my colleagues to oppose the bill.

1749 And I will ask for a recorded vote.

1750 But I didn't know if other members wanted to use --

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1751 Mr. Green. Mr. Chairman, ranking member yield?

1752 Mr. Pallone. I yield to Mr. Green.

1753 Mr. Green. I share the concern. Although, you know, when
1754 I looked at the bill it only goes from three to five years. But
1755 my concern is is if it does just impact one company. I guess,
1756 Mr. Chairman, that is why it would have been nice to have a public
1757 hearing on this particular draft or once it got a bill number so
1758 we could flesh it out. So that is lacking in what we are doing
1759 this day with the process.

1760 And the bill appears to be designed, I understand, for one
1761 company that has a product in the pipeline. And there are many
1762 non-opioid analgesics taken for post-surgical pain on the market
1763 that are low cost. My concern is that without the knowledge we
1764 have on it, we may be picking winners and losers on therapies on
1765 a bill that we don't have enough information on.

1766 And I thank my colleague for yielding to me.

1767 Mr. Pallone. I don't know if anybody else wants my time.

1768 Mr. Bucshon. Will the gentleman yield?

1769 Mr. Pallone. Yes. Yes, I will yield.

1770 Mr. Bucshon. It will be brief.

1771 The intent wasn't for, you know, to benefit one company. So
1772 we do have a verbal agreement to update the text to include current
1773 drugs on the market.

1774 I yield back.

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1775 Mr. Burgess. The chair thanks the gentleman for the
1776 clarification. Go take two aspirin and call me in the morning.

1777 Mr. Pallone. I yield back, Mr. Chairman, on that note.

1778 Mr. Green. We do have low cost pain medicine.

1779 Mr. Burgess. The gentleman yields back.

1780 The question now occurs -- Are there other members who wish
1781 to be heard on the legislation?

1782 Mr. Pallone. Mr. Chairman, I do ask for a recorded vote.

1783 Mr. Burgess. The question now occurs on forwarding the
1784 committee print to the full committee. The gentleman has asked
1785 for a recorded vote. The clerk will call the roll.

1786 The Clerk. Mr. Guthrie?

1787 Mr. Guthrie. Aye.

1788 The Clerk. Mr. Guthrie votes aye.

1789 Mr. Barton?

1790 [No response.]

1791 The Clerk. Mr. Upton?

1792 Mr. Upton. Aye.

1793 The Clerk. Mr. Upton votes aye.

1794 Mr. Shimkus?

1795 Mr. Shimkus. Aye.

1796 The Clerk. Mr. Shimkus votes aye.

1797 Mrs. Blackburn?

1798 Mrs. Blackburn. Aye.

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1799 The Clerk. Mrs. Blackburn votes aye.
1800 Mr. Latta?
1801 [No response.]
1802 The Clerk. Mrs. McMorris Rodgers?
1803 [No response.]
1804 The Clerk. Mr. Lance.
1805 Mr. Lance. Aye.
1806 The Clerk. Mr. Lance votes aye.
1807 Mr. Griffith?
1808 Mr. Griffith. Aye.
1809 The Clerk. Mr. Griffith votes aye.
1810 Mr. Bilirakis?
1811 Mr. Bilirakis. Aye.
1812 The Clerk. Mr. Bilirakis votes aye.
1813 Mr. Long?
1814 Mr. Long. Aye.
1815 The Clerk. Mr. Long votes aye.
1816 Mr. Bucshon?
1817 Mr. Bucshon. Aye.
1818 The Clerk. Mr. Bucshon votes aye.
1819 Mrs. Brooks.
1820 Mrs. Brooks. Aye.
1821 The Clerk. Mrs. Brooks votes aye.
1822 Mr. Mullin?

1823 Mr. Mullin. Aye.

1824 The Clerk. Mr. Mullin votes aye.

1825 Mr. Hudson?

1826 Mr. Hudson. Aye.

1827 The Clerk. Mr. Hudson votes aye.

1828 Mr. Collins?

1829 Mr. Collins. Aye.

1830 The Clerk. Mr. Collins votes aye.

1831 Mr. Carter?

1832 Mr. Carter. Aye.

1833 The Clerk. Mr. Carter votes aye.

1834 Mr. Walden?

1835 The Chairman. Aye.

1836 The Clerk. Mr. Walden votes aye.

1837 Mr. Green?

1838 Mr. Green. No.

1839 The Clerk. Mr. Green votes no.

1840 Mr. Engel?

1841 Mr. Engel. No.

1842 The Clerk. Mr. Engel votes no.

1843 Ms. Schakowsky?

1844 [No response.]

1845 The Clerk. Mr. Butterfield?

1846 Mr. Butterfield. No.

1847 The Clerk. Mr. Butterfield votes no.
1848 Ms. Matsui?
1849 [No response.]
1850 The Clerk. Ms. Castor?
1851 Ms. Castor. No.
1852 The Clerk. Ms. Castor votes no.
1853 Mr. Sarbanes?
1854 [No response.]
1855 The Clerk. Mr. Lujan?
1856 Mr. Lujan. No.
1857 The Clerk. Mr. Lujan votes no.
1858 Mr. Schrader?
1859 [No response.]
1860 The Clerk. Mr. Kennedy?
1861 Mr. Kennedy. No.
1862 The Clerk. Mr. Kennedy votes no.
1863 Mr. Cardenas?
1864 [No response.]
1865 The Clerk. Ms. Eshoo?
1866 Ms. Eshoo. Pass.
1867 The Clerk. Ms. Eshoo passes.
1868 Ms. DeGette?
1869 Ms. DeGette. No.
1870 The Clerk. Ms. DeGette votes no.

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1871 Mr. Pallone?

1872 Mr. Pallone. No.

1873 The Clerk. Mr. Pallone votes no.

1874 Chairman Burgess?

1875 Mr. Burgess. Aye.

1876 The Clerk. Chairman Burgess votes aye.

1877 Mr. Burgess. Mr. Latta.

1878 The Clerk. Mr. Latta has not voted.

1879 Mr. Latta. Aye.

1880 The Clerk. Mr. Latta votes aye.

1881 Mr. Burgess. Other members wishing to be recorded? The

1882 gentleman from Maryland.

1883 The Clerk. Mr. Sarbanes?

1884 Mr. Sarbanes. No.

1885 The Clerk. Mr. Sarbanes votes no.

1886 Ms. Schakowsky?

1887 Ms. Schakowsky. No.

1888 The Clerk. Ms. Schakowsky votes no.

1889 Mr. Burgess. How is Mr. Barton recorded?

1890 The Clerk. Mr. Barton is not recorded.

1891 Mr. Barton. Aye.

1892 Mr. Burgess. We are good. We are moving with a lot of

1893 dispatch. This is important stuff.

1894 The Clerk. Mr. Barton votes aye.

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1895 Mr. Burgess. Other members?

1896 The Clerk. Ms. Matsui is not recorded.

1897 Ms. Matsui. No.

1898 The Clerk. Ms. Matsui votes no.

1899 Mr. Burgess. Other members seeking to be recorded?

1900 [No response.]

1901 Mr. Burgess. If not, the clerk will call -- the clerk will

1902 report.

1903 The Clerk. Mr. Chairman, on that vote there are 18 ayes and

1904 11 noes.

1905 Mr. Burgess. Eighteen ayes, 11 noes, the committee print

1906 is forwarded to the full committee.

1907 The chair calls up H.R. 3528, that is Number 32 on the

1908 discussion draft list and asks the clerk to report.

1909 [The bill follows:]

1910

1911 ***** COMMITTEE INSERT 8 *****

1912 The Clerk. H.R. 3528, to Amend Title XVIII of the Social
1913 Security Act to require e-prescribing for coverage under part D
1914 of the Medicare program of prescription drugs that are controlled
1915 substances.

1916 Mr. Burgess. Without objection, the first reading of the
1917 bill is dispensed with and the bill is open for amendment at any
1918 point.

1919 So ordered.

1920 For what purpose does the gentleman from Oklahoma seek
1921 recognition?

1922 Mr. Mullin. Mr. Chairman, I would like to offer an
1923 amendment.

1924 Mr. Burgess. The clerk will report the amendment.

1925 The Clerk. Amendment to H.R. 3528 offered by Mr. Mullin.

1926 [The amendment of Mr. Mullin follows:]

1927

1928 ***** COMMITTEE INSERT 9 *****

1929 Mr. Burgess. Without objection the reading of the amendment
1930 is dispensed with and the gentleman is recognized for five minutes
1931 in support of his amendment.

1932 Mr. Mullin. Mr. Chairman, thank you so much.

1933 I would like to offer this amendment that would add an
1934 important exemption for long-term care pharmacies and protect
1935 some of our nation's most vulnerable citizens. Patients in
1936 long-term care are not asked -- are not at risk of having their
1937 drugs diverted or misused since the patients are confined to a
1938 facility where all their medication is prescribed, dispensed, and
1939 administered directly to them by their care team.

1940 Similar exemptions exist in state law where EPCS has been
1941 implemented. I am glad to support this change that helps our
1942 elderly and vulnerable nursing home patients. This amendment
1943 also gives patients the explicit right to choose where they access
1944 the prescriptions that have been electronically prescribed.
1945 Patients in rural and underserved areas often use community
1946 pharmacists, and this amendment ensures that electronic
1947 prescribing cannot be used to steer patients in any particular
1948 -- to any particular pharmacy by restricting them or the patient,
1949 and make sure they had the right to designate the pharmacy of their
1950 choice.

1951 With that, Mr. Chairman, I yield back.

1952 Mr. Burgess. The chair thanks the gentleman.

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1953 Other members wishing to be heard on the amendment?

1954 [No response.]

1955 Mr. Burgess. Seeing none, the question is on the adoption

1956 of the Mullin amendment.

1957 Those in favor, say aye.

1958 Those opposed, no.

1959 The amendment is agreed to.

1960 Is there further discussion of H.R. 3528?

1961 [No response.]

1962 Mr. Burgess. The question then occurs on forwarding H.R.

1963 3528, as amended, to the full committee.

1964 All those in favor, say aye.

1965 All those opposed, no.

1966 The ayes have it and the bill is agreed to.

1967 The chair calls up committee print entitled Mandatory

1968 Lock-in, Number 34 of the discussion draft, and asks the clerk

1969 to report.

1970 [The information follows:]

1971

1972 ***** COMMITTEE INSERT 10 *****

1973 The Clerk. Discussion Draft. To amend Title XVIII of the
1974 Social Security Act to require prescription drug plan sponsors
1975 under the Medicare program to establish drug management programs
1976 for at-risk beneficiaries.

1977 Mr. Burgess. Without objection, the first reading of the
1978 bill is dispensed with. The bill is open for amendment at any
1979 point. So ordered.

1980 Are there any bipartisan amendments to the bill?

1981 [No response.]

1982 Mr. Burgess. Are there members who wish to be heard on the
1983 bill? For what purpose does the gentleman from Florida seek
1984 recognition?

1985 Mr. Bilirakis. I ask to strike the last word.

1986 Mr. Burgess. The gentleman is recognized for five minutes.

1987 Mr. Bilirakis. Thank you, Mr. Chairman.

1988 Mr. Chairman, this bill is a simple tweak to the already
1989 existing Medicare lock-in program. Back in 2013, myself along
1990 with my good friend and colleague Ben Ray Lujan, introduced a
1991 Patient Safety and Drug Abuse Prevention Act which would create
1992 a pharmacy lock-in program in Medicare. This provision was
1993 ultimately included as part of the Comprehensive Addiction and
1994 Recovery Act of 2016, CARA.

1995 Pharmacy lock-in is not a new concept. States have been
1996 using physician or pharmacy lock-in, or some combination of both,

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1997 as part of the Medicare -- their Medicaid program for many, many
1998 years. TRICARE uses it, and so does commercial insurance.

1999 The law as it stands now has a "may" authority. This will
2000 change it to a "shall" authority.

2001 As one of the authors of the underlying bill, the law, the
2002 current law, our original language was a "shall" authority.
2003 Right now it is up to the discretion of the Part D plan that they
2004 may run a lock-in program or may not run a lock-in program. This
2005 legislation will take away that discretion and will require that
2006 all Part D plans must have a pharmacy lock-in program in place
2007 for at-risk beneficiaries. Again, just for at-risk
2008 beneficiaries.

2009 This is a common sense tweak to the law. Beneficiaries have
2010 the ability to switch plans every year, as most people know.
2011 At-risk beneficiaries would simply find prescription drug plans
2012 that do not have a lock-in program in place and use those plans
2013 to continue their drug diversion habits inside Medicare. We are
2014 trying to prevent that.

2015 This now ensures that we have a uniform system in place across
2016 Medicare Part D, and that all beneficiaries who are at risk can
2017 be identified and ensure that they receive assistance.

2018 In 2012, and we are talking, we are going way back, but an
2019 estimated 336,000 seniors had misused or become dependent on
2020 prescription pain relievers according to data from SAMHSA. And

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2021 you can imagine what it is now, Mr. Chairman. We need to do all
2022 we can to help our seniors in Medicare. This bill makes the law
2023 better. It has the support of the Administration. And I ask for
2024 swift passage of the bill. And I yield back.

2025 Mr. Burgess. The chair thanks the gentleman. The
2026 gentleman yields back.

2027 Other members wishing to be heard on this? For what purpose
2028 does the gentleman from New Mexico seek recognition?

2029 Mr. Lujan. Strike the last word, Mr. Chairman.

2030 Mr. Burgess. The gentleman is recognized for five minutes.

2031 Mr. Lujan. Thank you, Mr. Chairman.

2032 The bill we are considering today will build off of work done
2033 in the Comprehensive Addiction Recovery Act. The Medicare
2034 lock-in requires prescription drug plan sponsors under the
2035 Medicare program to establish drug management programs for
2036 at-risk beneficiaries. Unfortunately, CMS has not deployed this
2037 program to its fullest extent, both making sure that our seniors
2038 have access to pain medications, and making sure that we are not
2039 going to more than one pharmacies trying to maximize the number
2040 of prescriptions that we can get our hands on wherever possible.
2041 And this is very important.

2042 I generally enjoy working with my good friend Mr. Bilirakis,
2043 compliment his leadership not just on this issue but many others,
2044 and look forward to working with the committee on this provision.

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2045 And with that, I yield back.

2046 Mr. Burgess. Did you seek time?

2047 Mr. Lujan. I yield to Mr. Pallone.

2048 Mr. Burgess. The gentleman is recognized.

2049 Mr. Pallone. Thank you. I want to thank my colleague from
2050 New Mexico. I just had a few comments I would like to make
2051 regarding this discussion draft.

2052 It would require Part D sponsors to establish drug management
2053 programs, or what is often called lock-in programs. Permissive
2054 Part D lock-in requirements were first passed as part of the
2055 Comprehensive Addiction Recovery Act, or CARA. Building on this
2056 work, the intention of the bill is to require plan participation
2057 in a lock-in program in Medicare Part D.

2058 When implemented correctly, this policy could reduce the
2059 potential for abuse and diversion of opioids and other controlled
2060 substances, and could help to combat opioid addiction and misuse.
2061 However, I also recognize that we must ensure that beneficiary
2062 protections are in place to minimize the burdens this policy could
2063 have on beneficiaries when assessing needed medications.

2064 We received technical feedback on this discussion draft from
2065 CMS that speak to some of these concerns. And I believe we must
2066 be extremely careful when crafting this policy to ensure
2067 beneficiaries continue to have an appeal structure in place, as
2068 well as other needed protections.

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2069 Given the short time line for subcommittee markup
2070 consideration today since receiving that technical assistance,
2071 I think we still have a lot of work to do on this bill. And I
2072 hope to continue moving this policy forward and working with my
2073 Republican colleagues to come up with a solution that will help
2074 strengthen Part D plans' requirements for drug management
2075 programs, while also ensuring beneficiaries have the protections
2076 they need in order for a proposal like this to be successful.

2077 And I thank the gentleman and I yield back to the gentleman
2078 from New Mexico.

2079 Mr. Burgess. The chair thanks the gentleman. The
2080 gentleman yields back.

2081 Other members wishing to be heard?

2082 [No response.]

2083 Mr. Burgess. Seeing none, the question now occurs on
2084 forwarding the committee print to the full committee.

2085 All those in favor, say aye.

2086 All those opposed, no.

2087 The ayes appear to have it. The ayes have it. And the
2088 discussion draft is referred to the full committee.

2089 The chair calls up committee print entitled Beneficiary
2090 Education, Number 35 on the discussion draft list, and asks the
2091 clerk to report.

2092 [The information follows:]

2093

2094

***** COMMITTEE INSERT 11 *****

2095 The Clerk. Discussion draft. To amend Title XVIII of the
2096 Social Security Act to require prescription drug plans under
2097 Medicare part D to include information on the adverse effects of
2098 opioid overutilization and of coverage of nonpharmacological
2099 therapies or nonopioid medications or devices used to treat pain.

2100 Mr. Burgess. Without objection, the first reading of the
2101 bill is dispensed with and the bill is open for amendment at any
2102 point. So ordered.

2103 Are there bipartisan amendments to the bill?

2104 [No response.]

2105 Mr. Burgess. Are there other amendments to the bill? For
2106 what purpose does the gentlelady from Illinois seek recognition?

2107 Ms. Schakowsky. Mr. Chairman, I want to offer an amendment
2108 to address the --

2109 Mr. Burgess. Does the gentleman from -- Oh.

2110 Ms. Schakowsky. So I have an amendment at the desk.

2111 Mr. Burgess. The clerk will report.

2112 The Clerk. Amendment to discussion draft offered by Ms.
2113 Schakowsky.

2114 [The amendment of Ms. Schakowsky follows:]

2115

2116 ***** COMMITTEE INSERT 12 *****

2117 Mr. Collins. Mr. Chairman. Mr. Chairman.

2118 Mr. Burgess. Yes, for what purpose does the gentleman
2119 request recognition?

2120 Mr. Collins. I reserve a point of order against the
2121 amendment.

2122 Mr. Burgess. Chairman Collins reserves a point of order.
2123 Representative Schakowsky is recognized for five minutes in
2124 support of her amendment.

2125 Ms. Schakowsky. Thank you, Mr. Chairman.

2126 I offer this amendment to address the skyrocketing price of
2127 naloxone by giving the Secretary of HHS the authority to negotiate
2128 the price of naloxone. While I plan to withdraw this amendment,
2129 we must recognize that the cost of naloxone is a huge barrier to
2130 access. And when naloxone is not available, people die.

2131 Generic and brand formulations of this drug has seen huge
2132 price increases within the last few years. With the increased
2133 demand on these drugs to equip police, emergency medical
2134 providers, schools, families, and friends the burden on the public
2135 programs has increased as well. Pharmaceutical corporations
2136 have unchecked power to raise the price of their drugs as much
2137 as they want. In the case of naloxone, access to the drug is
2138 literally a life or death difference.

2139 This is a public health emergency, and we must ensure that
2140 the Department of Health and Human Services has every tool it needs

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2141 to address, to address the crisis. That includes allowing the
2142 Secretary to negotiate the price of this life-saving drug.
2143 Naloxone is a prescription drug also known by its brand name Narcan
2144 or Evzi -- what is it, Evzio? -- Evzio, that can quickly reverse
2145 the opioid overdose. Naloxone can bring someone back to life
2146 within minutes.

2147 There are two versions of the drug: injectables and nasal
2148 sprays. The cost of generic injectable naloxone, which has been
2149 on the market since 1971, has been climbing. A 10 millimeter vial
2150 sold costs close to \$150, more than double its price from even
2151 a few years ago, and far beyond the production costs of the
2152 naloxone chemical.

2153 Even more egregious is Kaleo, the pharmaceutical corporation
2154 that produces Evzio, accounted for nearly 20 percent of the
2155 naloxone dispensed, has raised its twin pack price from \$690 in
2156 2014 to, get this, \$4,500 today. This is a 500 percent increase.
2157 This price surge is way out of step with production costs, a
2158 needless strain on healthcare resources, and stopping many from
2159 accessing the drug.

2160 I believe that the Secretary of HHS should have the authority
2161 to negotiate all drug prices. Like President Trump says, "We are
2162 the largest buyer of drugs in the world, and yet, we don't bid
2163 properly." Medicare price negotiations is how we can bid
2164 properly, especially though in the case for naloxone where the

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2165 public need is so great and prices continue to rise with no
2166 explanation or regard for human life.

2167 We can't allow pharmaceutical corporations to profit off
2168 this epidemic. It is unacceptable and it is happening. It is
2169 unacceptable to the 115 Americans that die every day from opioid
2170 overdoses, and it is unacceptable because it was the
2171 pharmaceutical corporations that were dumping pills, over 20
2172 million opioid pills to a town of about 3,000 people.
2173 Pharmaceutical corporations cannot start this -- cannot stop this
2174 epidemic with irresponsible, irresponsible, reckless pill
2175 dumping one day and then turn around and profit off it the next.
2176 We can't stand for that.

2177 So, while I am withdrawing this amendment, I encourage all
2178 of my colleagues to adopt my next amendment that will ask for a
2179 study, at the very least a study to figure out why these drugs
2180 are so unaffordable.

2181 I thank you. And I withdraw my amendment.

2182 Mr. Burgess. Without objection, the amendment is
2183 withdrawn.

2184 Are there other amendments to the bill?

2185 [No response.]

2186 Mr. Burgess. Other discussion of the bill? For what
2187 purpose does the gentleman from Kentucky seek recognition?

2188 Mr. Guthrie. Mr. Chairman, I move to strike the last word.

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2189 Mr. Burgess. The gentleman is recognized for five minutes.

2190 Mr. Guthrie. Thank you, Mr. Chairman. I want to speak on
2191 this bill.

2192 This bill requires plans to annually notify beneficiaries
2193 of the adverse effects associated with prolonged opioid use, as
2194 well as non-opioid pains management options under Medicare. It
2195 is important that we try to address this epidemic at all levels,
2196 and providing educational outreach to beneficiaries is an
2197 important component. The more we empower beneficiaries to make
2198 informed decisions about their healthcare and how to engage their
2199 providers, the better.

2200 We look forward to working with stakeholders as we move to
2201 full committee to ensure this outreach is targeted, effective,
2202 and not unnecessarily burdensome. I urge my colleagues to
2203 support this bill and continue this bipartisan discussion.

2204 And unless someone needs my time, I yield back.

2205 Mr. Burgess. The gentleman yields back.

2206 Other members wishing to be heard on the bill?

2207 [No response.]

2208 Mr. Burgess. Seeing none, the --

2209 Ms. Schakowsky. Mr. Chairman, I have another amendment at
2210 the desk.

2211 Oh, I do not on this bill. I am sorry.

2212 Mr. Burgess. Very well. Other members wishing to be heard?

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2213 [No response.]

2214 Mr. Burgess. Seeing none, the question now occurs on
2215 forwarding the committee print to the full committee.

2216 All those in favor, say aye.

2217 All those opposed, no.

2218 The ayes appear to have it. The ayes have it. And the bill
2219 is agreed to and forwarded to the full committee.

2220 The chair calls up the committee print entitled Evaluating
2221 Abuse Deterrent Formulations, Number 36 on the discussion draft
2222 list, and asks the clerk to report.

2223 [The information follows:]

2224

2225 ***** COMMITTEE INSERT 13 *****

2226 The Clerk. Discussion draft. To direct the Secretary of
2227 Health and Human Services to conduct a study and submit a report
2228 on barriers to accessing abuse-deterrent opioid formulations for
2229 individuals enrolled in a plan under part C or D of the Medicare
2230 program.

2231 Mr. Burgess. Without objection, the first reading of the
2232 bill is dispensed with. The bill will be open for amendment at
2233 any point. So ordered.

2234 Are there bipartisan amendments to the bill?

2235 [No response.]

2236 Mr. Burgess. Are there other amendments?

2237 Ms. Schakowsky. Mr. Chairman, I have an amendment to this
2238 bill.

2239 Mr. Burgess. The clerk will report the amendment.

2240 The Clerk. Amendment to Discussion Draft offered by Ms.
2241 Schakowsky.

2242 [The amendment of Ms. Schakowsky follows:]

2243

2244 ***** COMMITTEE INSERT 14 *****

2245 Mr. Collins. Mr. Chairman, I have a point of order. I
2246 reserve a point of order against the amendment.

2247 Mr. Burgess. The gentleman from New York reserves a point
2248 of order.

2249 Representative Schakowsky is recognized for five minutes in
2250 support of her amendment.

2251 Ms. Schakowsky. So, as I was saying in the last amendment
2252 that I have withdrawn, the price of lifesaving opioid overdose
2253 reserve drug naloxone is too high. This amendment calls on the
2254 Secretary of Health and Human Services to study exactly how this
2255 happened and make recommendations on how it can lower prices for
2256 consumers.

2257 The price of naloxone is a huge barrier to these critically
2258 important drugs. We must have a better understanding of how they
2259 are priced and find solutions. We must check their power of the
2260 pharmaceutical corporations. We must know how these drugs are
2261 priced and have recommendations to bring the price down.
2262 Lowering the cost to this drug will literally save lives. And
2263 that is what I thought we were about today.

2264 And so I certainly urge my colleagues on both sides to just,
2265 to vote yes on this amendment. This is simply asking the
2266 Department of Health and Human Services to do a study to take a
2267 look at why this drug is not more easily available, why it can't
2268 be made more accessible, and why we can't save more lives.

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2269 We need to give our first responders the tools they need to
2270 treat opioid overdoses. And lowering the cost of these drugs is
2271 a critical step in that fight.

2272 Mr. Pallone. Will the gentlewoman yield?

2273 Ms. Schakowsky. And I would yield to our ranking member.

2274 Mr. Pallone. I want to support Representative Schakowsky's
2275 amendment. Naloxone, as we know, is an antidote to opioid
2276 overdoses first approved by the FDA in 1971, and has the ability
2277 to bring those who have overdosed back in seconds. However, the
2278 cost of this powerful treatment has spiked dramatically in recent
2279 years, threatening patient, caregiver, law enforcement, and
2280 emergency access.

2281 For example, the cost of a 2-pack naloxone injector has
2282 increased more than 600 percent from \$690 in 2014 to \$4,500 last
2283 year. Injectable and nasal sprays versions of naloxone have also
2284 nearly doubled. These price hikes are irresponsible as cities
2285 across the country are scrambling to respond to the crisis. Each
2286 day 116 people have died from opioid-related drug overdoses,
2287 making access to naloxone even more critical. Clearly, something
2288 has to be done.

2289 The amendment by Ms. Schakowsky would direct the Secretary
2290 to conduct a study on the rising prices and provide Congress
2291 recommendations on ways to lower prices. And this is just a
2292 common sense amendment that will put us on a path to ensuring

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2293 stable pricing and greater access to this lifesaving medication.
2294 So I just would hope that my colleagues would join me in supporting
2295 Ms. Schakowsky's amendment.

2296 I yield back to her.

2297 Ms. Schakowsky. And I yield some time to Congressman Engel.

2298 Mr. Engel. Thank you. I thank Congresswoman Schakowsky
2299 for offering this amendment. As I said in my opening statement,
2300 I represent a large portion of Westchester County, New York, where
2301 opioid-related deaths shot up more than 200 percent between 2010
2302 and 2015. But in 2016, the rate of opioid-related deaths in
2303 Westchester fell nearly by 30 percent. Evidence shows this was
2304 thanks to the overdose reversal drug naloxone.

2305 Before 2015 and 2016, Westchester EMS workers and law
2306 enforcement began using naloxone much more frequently following
2307 state and local efforts to make naloxone more accessible and
2308 ensure first responders know how to use it. Now, this drug is
2309 not a panacea. In this epidemic we must support proven public
2310 health approaches spanning the entire spectrum from prevention
2311 to recovery. The Westchester example shows the difference
2312 greater access to naloxone can make even in a short period of time.
2313 Therefore, having HHS examine the rising prices that could pose
2314 a barrier for people to access this lifesaving drug to me makes
2315 good sense.

2316 So I urge my colleagues to support this amendment. And I

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2317 yield back the balance of my time. I yield back to Ms. Schakowsky.

2318 Ms. Schakowsky. Thank you. I would hope that my colleagues
2319 on the other side of the aisle would acknowledge this problem.
2320 We are here today because we have an opportunity to save lives.
2321 And when a drug has been on the market for a long time, goes from
2322 \$690 to \$4,500, something is happening here that shouldn't be
2323 happening.

2324 So I really, I really plead with you to not oppose this; to
2325 say, yes, we are going to save lives, and make this lifesaving
2326 drug affordable.

2327 And I yield back.

2328 Mr. Burgess. The gentlelady --

2329 Ms. Schakowsky. And just do a study about it.

2330 Mr. Burgess. -- yields back.

2331 Any other member wishing to be heard on the Schakowsky
2332 amendment? The gentlelady from California. For what purpose do
2333 you seek recognition?

2334 Ms. Eshoo. Strike the last word.

2335 Mr. Burgess. The gentlelady is recognized for five minutes.

2336 Ms. Eshoo. Thank you, Mr. Chairman.

2337 I support the amendment. There has to be some explanation
2338 for this. And I really think everyone needs to be open to it.
2339 I don't know how any of us can look at our constituents straight
2340 in the eye and say, well, something that was helpful and working

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2341 is available just a handful of years ago for four hundred and some
2342 odd dollars and now it is four thousand some odd dollars. So it
2343 makes, just makes sense.

2344 I don't know how long it is going to take for the department
2345 to respond to or study this. I don't know if we have any idea.
2346 If we do, I would like to know.

2347 I would also like to just, if someone could tell me on the
2348 discussion draft for requiring prescription drug plans under
2349 Medicare Part D, is that a label? I didn't get to ask that
2350 question. Is it a label that says that the therapies, devices,
2351 et cetera, used to treat pain needs to be, that information needs
2352 to be included? Is that what that means in terms of beneficiary
2353 education?

2354 I don't know what the answer to that is. But if someone
2355 could, maybe the maker of that could answer that question.

2356 But I think I don't know what is so -- I think that this
2357 amendment of Ms. Schakowsky's is something that is non-partisan.
2358 And I don't think that we are helping our constituents if it falls
2359 along partisan lines. There is something not right about this
2360 and we should look into it, get an answer. If we don't agree with
2361 what the agency comes up with, we can debate it at that time. But
2362 to go from four hundred and some dollars to four thousand something
2363 is, that is a pretty big question mark.

2364 So I yield back. Thank you. Answer to that question about

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2365 the beneficiary education issue I would appreciate it.

2366 Mr. Burgess. The gentlelady yield back.

2367 Other members wishing to be heard on the amendment? For what
2368 purpose does the gentleman from Georgia seek recognition?

2369 Mr. Carter. Mr. Chairman, move to strike the last word.

2370 Mr. Burgess. The gentleman is recognized for five minutes.

2371 Mr. Carter. Mr. Chairman, I appreciate my colleagues'
2372 interest in expanding access to naloxone by directing HHS to study
2373 its pricing and develop recommendations to lower its cost.

2374 However, naloxone is a critical part of our nation's response to
2375 the opioid crisis and should be readily available. However, this
2376 amendment is not germane. It is not germane to the intent of this
2377 legislation.

2378 This legislation is focused on reviewing barriers to access
2379 to abuse-deterrent formulations for Medicare Part C and D chronic
2380 pain patients. While I fully understand the need to ensure
2381 naloxone is available, the bill should remain as written.

2382 And I yield back.

2383 Mr. Burgess. The gentleman yields back.

2384 Other members wishing to be heard?

2385 Ms. Schakowsky. Mr. Chairman, can I respond to the issue
2386 of germaneness?

2387 Mr. Burgess. Will the gentleman from Georgia yield to the
2388 gentlelady from Illinois?

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2389 Mr. Carter. I yield.

2390 Ms. Schakowsky. So I am looking at this brief synopsis of
2391 the underlying bill. And it says the discussion draft would
2392 require the Secretary to study and report to Congress, yadada,
2393 yadada.

2394 My bill is to study and report to Congress on something also
2395 relevant to the issue at hand, which is the opioid crisis. So
2396 it seems to me that in word and in thought that this is completely
2397 germane to today's discussion. And to find a loophole to say not,
2398 just seems to me not addressing what we are really here to do today.

2399 Mr. Carter. Reclaiming my time, Mr. Chairman.

2400 Mr. Chairman, first of all, we have moved past the discussion
2401 draft. We have moved past the discussion draft here. And this
2402 bill is to address the abuse deterrent access formulations. This
2403 is not germane to the discuss -- to this bill as it is now.

2404 Ms. Schakowsky. Still directing a study and a report.

2405 Mr. Burgess. Does the gentleman yield back?

2406 Mr. Carter. Mr. Chairman, reclaiming my time.

2407 The gentlelady is trying to address something that happens
2408 after the fact. What we are addressing in this bill is
2409 abuse-deterrent formulations. This is something that is going
2410 to impact patients before the fact. So we are talking about two
2411 different things here.

2412 Ms. Schakowsky. If I could respond one more time.

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2413 Look, I think that what I am hearing, or at least what I have
2414 decided I am hearing is that you think there is some merit in this
2415 amendment that I am offering, even though you are saying it is
2416 not germane. So the question is, if I were to introduce my
2417 amendment as a standalone bill, you know, would, would my
2418 colleagues on the other side of the aisle vote for it? Or are
2419 you going to find another loophole to say that it is not germane
2420 or it is not appropriate or you just don't like it?

2421 And this is such a simple idea that I can't see why you
2422 wouldn't figure out how we can fold it into this piece of
2423 legislation.

2424 Mr. Carter. Mr. Chairman, reclaiming my time.

2425 Mr. Burgess. The gentleman is recognized.

2426 Mr. Carter. Mr. Chairman, Mr. Chairman, I would yield to
2427 Mr. Collins.

2428 Mr. Collins. I insist on my point of order.

2429 Mr. Burgess. The chair would ask if the gentlelady will
2430 withdraw her amendment and --

2431 Ms. Schakowsky. No. I would ask for, I would ask for a
2432 vote.

2433 Mr. Burgess. -- -we will work with you?

2434 If you wish to have your vote, you may have your vote. If
2435 you will withdraw the amendment we can continue to work.

2436 Ms. Schakowsky. Let's have a vote on that. And I would like

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2437 to work with you then on the --

2438 Mr. Collins. Point of order, Mr. Chairman.

2439 Ms. Schakowsky. -- on moving this forward.

2440 Mr. Burgess. The chair would rule, the gentleman insists
2441 on his point of order. Having reviewed the amendment, the chair
2442 finds the amendment is not germane because it would bring a matter
2443 not addressed in the underlying bill. Therefore, the chair
2444 sustains the point of order.

2445 Mr. Carter. Mr. Chairman.

2446 Mr. Burgess. The gentleman from Georgia.

2447 Mr. Carter. Strike the last word to speak on the bill.

2448 Ms. Schakowsky. Mr. Chairman. Oh. I would like to appeal
2449 the ruling of the chair.

2450 Mr. Burgess. The gentlelady, would the gentlelady --

2451 Mr. Carter. I move to table the appeal.

2452 Mr. Burgess. The gentleman moves to table. The question
2453 is on tabling the appeal of the ruling of the chair.

2454 Those in favor, say aye.

2455 Those opposed, no.

2456 Ms. Schakowsky. I would like a recorded vote.

2457 Mr. Burgess. Roll call is requested. The clerk will call
2458 the role.

2459 The Clerk. Mr. Guthrie?

2460 Mr. Guthrie. Aye.

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2461 The Clerk. Mr. Guthrie votes aye.
2462 Mr. Barton?
2463 [No response.]
2464 The Clerk. Mr. Upton?
2465 Mr. Upton. Aye.
2466 The Clerk. Mr. Upton votes aye.
2467 Mr. Shimkus?
2468 Mr. Shimkus. Aye.
2469 The Clerk. Mr. Shimkus votes aye.
2470 Mrs. Blackburn?
2471 Mrs. Blackburn. Aye.
2472 The Clerk. Mrs. Blackburn votes aye.
2473 Mr. Latta?
2474 Mr. Latta. Aye.
2475 The Clerk. Mr. Latta votes aye.
2476 Mrs. McMorris Rodgers?
2477 [No response.]
2478 The Clerk. Mr. Lance.
2479 [No response.]
2480 The Clerk. Mr. Griffith?
2481 Mr. Griffith. Aye.
2482 The Clerk. Mr. Griffith votes aye.
2483 Mr. Bilirakis?
2484 Mr. Bilirakis. Aye.

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2485 The Clerk. Mr. Bilirakis votes aye.
2486 Mr. Long?
2487 Mr. Long. Aye.
2488 The Clerk. Mr. Long votes aye.
2489 Mr. Bucshon?
2490 Mr. Bucshon. Aye.
2491 The Clerk. Mr. Bucshon votes aye.
2492 Mrs. Brooks.
2493 Mrs. Brooks. Aye.
2494 The Clerk. Mrs. Brooks votes aye.
2495 Mr. Mullin?
2496 Mr. Mullin. Aye.
2497 The Clerk. Mr. Mullin votes aye.
2498 Mr. Hudson?
2499 [No response.]
2500 The Clerk. Mr. Collins?
2501 Mr. Collins. Aye.
2502 The Clerk. Mr. Collins votes aye.
2503 Mr. Carter?
2504 Mr. Carter. Aye.
2505 The Clerk. Mr. Carter votes aye.
2506 Chairman Walden?
2507 [No response.]
2508 The Clerk. Mr. Green?

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2509 Mr. Green. No.

2510 The Clerk. Mr. Green votes no.

2511 Mr. Engel?

2512 Mr. Engel. No.

2513 The Clerk. Mr. Engel votes no.

2514 Ms. Schakowsky?

2515 Ms. Schakowsky. No.

2516 The Clerk. Ms. Schakowsky votes no.

2517 Mr. Butterfield?

2518 Mr. Butterfield. No. The Clerk.

2519 Mr. Butterfield votes no.

2520 Ms. Matsui?

2521 Ms. Matsui. No.

2522 The Clerk. Ms. Matsui votes no.

2523 Ms. Castor?

2524 Ms. Castor. No.

2525 The Clerk. Ms. Castor votes no.

2526 Mr. Sarbanes?

2527 Mr. Sarbanes. No.

2528 The Clerk. Mr. Sarbanes votes no.

2529 Mr. Lujan?

2530 [No response.]

2531 The Clerk. Mr. Schrader?

2532 Mr. Schrader. No.

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2533 The Clerk. Mr. Schrader votes no.
2534 Mr. Kennedy?
2535 Mr. Kennedy. No.
2536 The Clerk. Mr. Kennedy votes no.
2537 Mr. Cardenas?
2538 [No response.]
2539 The Clerk. Ms. Eshoo?
2540 Ms. Eshoo. No.
2541 The Clerk. Ms. Eshoo votes no.
2542 Ms. DeGette?
2543 Ms. DeGette. No.
2544 The Clerk. Ms. DeGette votes no.
2545 Mr. Pallone?
2546 Mr. Pallone. No.
2547 The Clerk. Mr. Pallone votes no.
2548 Chairman Burgess?
2549 Mr. Burgess. Aye.
2550 The Clerk. Chairman Burgess votes no. Mr. Burgess,
2551 Chairman Burgess votes aye.
2552 Chairman Walden is not recorded.
2553 The Chairman. Aye.
2554 The Clerk. Chairman Walden votes aye.
2555 Mr. Burgess. The gentleman from Texas?
2556 Mr. Barton. Aye.

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2557 The Clerk. Mr. Barton votes aye.

2558 Mr. Burgess. The gentleman from New Jersey?

2559 The Clerk. Mr. Lance?

2560 Mr. Lance. Aye.

2561 The Clerk. Mr. Lance votes aye.

2562 Mr. Burgess. The gentleman from New Mexico.

2563 Mr. Hudson. Aye.

2564 The Clerk. Mr. Hudson votes aye.

2565 Mr. Lujan votes no.

2566 Mr. Burgess. Other members wishing to be recorded?

2567 [No response.]

2568 Mr. Burgess. Seeing none, the clerk will report the total.

2569 The Clerk. Mr. Chairman, on that vote there were 18 ayes
2570 and 13 noes.

2571 Mr. Burgess. I am sorry. Can I ask the clerk to report.
2572 There was a conversation up here.

2573 The Clerk. Mr. Chairman, on that vote there were 18 ayes
2574 and 13 noes.

2575 Mr. Burgess. Eighteen ayes, 13 noes, the motion is tabled.

2576 Other amendments to the legislation or further discussion
2577 of the bill? For what purpose does the gentleman from New Jersey
2578 seek recognition?

2579 Mr. Pallone. To strike the last word on the underlying bill,
2580 Mr. Chairman.

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2581 Mr. Burgess. The gentleman is recognized for five minutes.

2582 Mr. Pallone. Just a few comments. This bill requires HHS
2583 to conduct a study and submit to Congress a report on the adequacy
2584 of access to abuse-deterrent opioid formulations for individuals
2585 with chronic pain enrolled in Medicare Advantage or Part D. And
2586 while I appreciate the intent of the bill, I want to highlight
2587 the fact that while abuse-deterrent formulations are an important
2588 technological advancement, we must not forget that these
2589 medications are no less addictive in abuse-deterrent form.

2590 Abuse-deterrent formulations make it more difficult to crush
2591 up, dissolve, or further manipulate prescription opioid for
2592 diverted purposes such as snorting or injecting. However, these
2593 formulations have no impact when opioid are being utilized for
2594 intentional therapeutic uses, which can also lead to opioid
2595 dependence and misuse.

2596 So I just want to caution my colleagues from relying too
2597 heavily on abuse-deterrent formulations or believing that these
2598 formulations will result in lower opioid abuse rates than
2599 non-abuse-deterrent formulated drugs. As we move forward
2600 towards full committee consideration I look forward to continuing
2601 to work with my Republican colleagues on this legislation.

2602 But also recognize that a report to Congress on this issue
2603 may illuminate some of the concerns that I have highlighted.

2604 And with that I yield back, Mr. Chairman, unless the -- I

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2605 yield --

2606 Ms. DeGette. Will the gentleman yield?

2607 Mr. Pallone. -- to the gentlewoman from Colorado.

2608 Ms. DeGette. I thank the gentleman for yielding. Mr.

2609 Chairman, I just, if I may engage in a brief colloquy with you

2610 since this is a discussion draft. I am just I am sitting here

2611 reading the summary of the bill. And it looks like a really good

2612 idea to me. And it looks like something that I am prepared to

2613 support.

2614 I am just wondering if you can tell me why it is not a bill

2615 and why it is a discussion draft, and what it is we propose to

2616 do with this language between now and the full markup? I am just

2617 -- and I am saying that honestly because this seems to me like

2618 it could just be a straightforward bill that we would vote on.

2619 And I don't really understand why we don't have it as a bill, why

2620 it is a discussion draft.

2621 Mr. Burgess. Will the gentlelady yield?

2622 Ms. DeGette. Yes, Mr. Chairman.

2623 Mr. Burgess. Well, the discussion draft is a discussion

2624 draft because the bill has not been introduced yet. It is not

2625 unusual to have --

2626 Ms. DeGette. Right.

2627 Mr. Carter. Mr. Chairman, the bill was introduced Monday.

2628 Ms. DeGette. Well, then reclaiming Mr. Pallone's time, if

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2629 a bill was introduced Monday why are we marking up a discussion
2630 draft? Is it a bill? Is this the bill, the discussion draft,
2631 the bill that was introduced on Monday?

2632 Mr. Burgess. The committee had prepared the discussion
2633 draft. I was not aware the gentleman had introduced the bill.

2634 Ms. DeGette. So the bill we are marking up is actually the
2635 bill that was introduced on Monday?

2636 Mr. Carter. Yes, it is.

2637 Ms. DeGette. Okay, thank you. See, this is why I just have
2638 problems with this process because it is really confusing to try
2639 to mark up something you don't even know if it has been introduced.
2640 So I will just, I will just say that. And I yield back.

2641 Mr. Burgess. The gentlelady yields back.

2642 Further discussion on the bill?

2643 [No response.]

2644 Mr. Burgess. Seeing none, the question then is on favorably
2645 reporting the bill to the full committee.

2646 All those in favor, say aye.

2647 All those opposed, no.

2648 The ayes have it. And the bill is agreed to and forwarded
2649 to the full committee.

2650 Now is in order to observe that we worked with the minority
2651 to consider a number of bills and forward to the full committee
2652 by unanimous consent. And we thank the minority and we thank the

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2653 minority staff for working with us on this.

2654 Before we proceed I wanted to recognize the ranking member
2655 of the full committee to speak for five minutes on this group of
2656 bills.

2657 Mr. Pallone. Thank you, Mr. Chairman. Is this working? I
2658 guess so.

2659 I move to strike the last word and speak in favor of moving
2660 forward the selected bills we are considering en bloc. Included
2661 in this en bloc package of bills is H.R. 449, the Synthetic Drug
2662 Awareness Act, which would require the Surgeon General to report
2663 to Congress on the health impacts of synthetic drug usage by teens
2664 age 12 to 18.

2665 Additionally this en bloc package includes H.R. 4841, which
2666 provides technical standards for electronic prior authorization
2667 requests for covered part D drugs.

2668 In addition to these two bills, this en bloc package includes
2669 two discussion drafts, one that would add educational resources
2670 on opioid use and alternatives to opioids to the Medicare & You
2671 Handbook; and another to require CMS to provide for an action plan
2672 on recommendations for changes to Medicare and Medicaid to prevent
2673 opioid addiction and enhance access to medication-assisted
2674 treatment.

2675 And finally, as part of this en bloc package we are
2676 considering several discussion drafts related to Medicare Part

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2677 D.

2678 As I noted in my opening statement earlier this afternoon,
2679 I remain very concerned regarding the condensed time frame in
2680 which we are working to finalize the dozens of bills we are
2681 currently considering. Many of the bills remain in discussion
2682 draft form for subcommittee markup today, including four that we
2683 are considering en bloc before us now.

2684 Late last week, CMS provided technical feedback on these
2685 bills in either verbal or written form, but these discussion
2686 drafts are still just that, drafts, and a work in progress. We
2687 have not had time to fully evaluate the TA provided, the technical
2688 assistance provided. And these bills will need further
2689 revisions, stakeholder input, CBO scores, and thoughtful review.
2690 However, given the time constraints, we have not been able to
2691 complete these vital steps first.

2692 I would also like to note that I have significant concerns
2693 about some of the language in the CMS Action Plan draft. While
2694 I agree in principle that CMS should take further action to
2695 incentivize use of medication-assisted treatment and opioid
2696 alternatives, I think it is bad policy to start unbundling drugs
2697 and other therapies from our bundle of pain assistance for
2698 hospitals. There is no evidence that such an approach would do
2699 anything to stem the opioid epidemic. It would also raise drug
2700 costs throughout our healthcare system, as well as beneficiary

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2701 cost sharing.

2702 I don't think this is a good use of taxpayer dollars. And
2703 I urge Chairman Walden and the bill's co-sponsors to work with
2704 us to address this shortcoming in the bill. But, in the hopes
2705 of reaching bipartisan consensus on these policies, and in order
2706 to find solutions that could make a positive impact, I would like
2707 to see these bills advance to full committee so we can continue
2708 to have the necessary discussions and ensure that these proposals
2709 have had sufficient consideration and input.

2710 And it is my hope that I can fully support each of these
2711 policies as the process moves forward, but we must keep working.
2712 I stand ready to work with my colleagues on these proposals, but
2713 also recognize that until these policies receive the vetting
2714 needed I remain concerned.

2715 So, for these reasons at this time I would urge my colleagues
2716 to support advancing these proposals en bloc so we can continue
2717 the work that has been started.

2718 And, Mr. Chairman, let me just say I am not sure that all
2719 the members are aware of exactly what we are moving en bloc. So
2720 should I just go through that list or do you want to do it? I
2721 mean, I have the list here but I want to make sur that everyone
2722 knows what we are doing.

2723 Mr. Burgess. The chair was prepared to go through the list.

2724 Mr. Pallone. Would you do that? Thank you, Mr. Chairman.

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2725 Mr. Burgess. So would the gentleman yield back?

2726 Mr. Pallone. Yes.

2727 Mr. Burgess. And I thank the gentleman for his comments and
2728 the spirit with which he has indicated that he will continue to
2729 work with us on this side of the dais.

2730 I ask unanimous consent that the subcommittee forward the
2731 committee print entitled CMS Action Plan Number 25 to the full
2732 committee.

2733 [The information follows:]

2734

2735 ***** COMMITTEE INSERT 15 *****

2736 Mr. Burgess. Without objection, so ordered.

2737 I ask unanimous consent that the subcommittee forward the
2738 committee print entitled Adding Resources on Non-Opioid
2739 Alternatives to the Medicare Handbook, Number 27 in the committee
2740 print list to the full committee.

2741 [The information follows:]

2742

2743 ***** COMMITTEE INSERT 16 *****

2744 Mr. Burgess. Without objection, so ordered.

2745 I ask unanimous consent that the subcommittee forward H.R.
2746 4841, which previously was Number 33 on the discussion draft list,
2747 to the full committee.

2748 [The bill follows:]

2749

2750 ***** COMMITTEE INSERT 17 *****

2751 Mr. Burgess. Without objection, so ordered.

2752 I ask unanimous consent that the subcommittee forward the
2753 committee print entitled Prescriber Notification, Number 37 on
2754 the discussion draft list, to the full committee.

2755 [The information follows:]

2756

2757 ***** COMMITTEE INSERT 18 *****

2758 Mr. Burgess. Without objection, so ordered.

2759 I ask unanimous consent that the subcommittee forward the
2760 committee print entitled Prescriber Education, Number 38 on the
2761 discussion draft list, to the full committee.

2762 [The information follows:]

2763

2764 ***** COMMITTEE INSERT 19 *****

2765 Mr. Burgess. Without objection, so ordered.

2766 I ask unanimous consent that the subcommittee forward the
2767 committee print entitled Medication Therapy Management
2768 Expansion, Number 39 on the discussion draft list, to the full
2769 committee.

2770 [The information follows:]

2771

2772 ***** COMMITTEE INSERT 20 *****

2773 Mr. Burgess. Without objection, so ordered.

2774 I ask unanimous consent that the subcommittee forward the
2775 committee print entitled CMS Plan Sharing, Number 40 on the
2776 discussion draft list, to the full committee.

2777 [The information follows:]

2778

2779 ***** COMMITTEE INSERT 21 *****

2780 Mr. Burgess. Without objection, so ordered.

2781 I ask unanimous consent that the subcommittee forward H.R.
2782 449, Number 6 on the discussion draft list, with the amendment
2783 filed by Mr. Green, to the full committee.

2784 [The bill follows:]

2785

2786 ***** COMMITTEE INSERT 22 *****

2787 Mr. Burgess. Without objection, so ordered.

2788 I ask unanimous consent that the subcommittee forward H.R.
2789 5002, Number 11 on the discussion draft list, to the full
2790 committee.

2791 [The bill follows:]

2792

2793 ***** COMMITTEE INSERT 23 *****

2794 Mr. Burgess. Without objection, so ordered.

2795 I ask unanimous consent that the subcommittee forward H.R.
2796 5009, Number 12 on the discussion draft list to the full committee.

2797 [The bill follows:]

2798

2799 ***** COMMITTEE INSERT 24 *****

2800 Mr. Burgess. Without objection, so ordered.

2801 I ask unanimous consent that the subcommittee forward H.R.
2802 5102, Number 13 on the discussion draft list, to the full
2803 committee.

2804 [The bill follows:]

2805

2806 ***** COMMITTEE INSERT 25 *****

2807 Mr. Burgess. Without objection, so ordered.

2808 I ask unanimous consent that the subcommittee forward H.R.
2809 5261, number 16, with the amendment filed by Mr. Burgess, to the
2810 full committee.

2811 [The bill follows:]

2812

2813 ***** COMMITTEE INSERT 26 *****

2814 Mr. Burgess. Without objection, so ordered.

2815 I ask unanimous consent that the subcommittee forward the
2816 committee print entitled To Improve Fentanyl Testing and
2817 Surveillance, Number 22 on the discussion draft list, to the full
2818 committee.

2819 [The information follows:]

2820

2821 ***** COMMITTEE INSERT 27 *****

2822 Mr. Burgess. Without objection, so ordered.

2823 So there is a vote on the floor. But I think we are going
2824 to consider one additional bill.

2825 The chair calls up H.R. 1925, Number 41 on the discussion
2826 draft list, and asks the clerk to report.

2827 [The bill follows:]

2828

2829 ***** COMMITTEE INSERT 28 *****

2830 The Clerk. H.R. 1925, To Amend Title XIX of the Social
2831 Security Act to protect at risk youth against termination of
2832 Medicaid eligibility while an inmate of a public institution.

2833 Mr. Burgess. Without objection, the first reading of the
2834 bill is dispensed with. And the bill is open for amendment at
2835 any point.

2836 So ordered.

2837 Are there bipartisan amendments to the bill?

2838 [No response.]

2839 Mr. Burgess. Are there amendments to the bill?

2840 [No response.]

2841 Mr. Burgess. Does any member wish to speak on the bill? The
2842 gentleman from Virginia is recognized.

2843 Mr. Griffith. I think the concept of this is good and it
2844 ought to be moved forward, Mr. Chairman. This has been a concern.
2845 And what happens is is that when a juvenile goes into a facility
2846 their benefits get terminated. And then they have to go through
2847 the whole application process again. If you suspend them, that
2848 doesn't happen.

2849 Mr. Burgess. The gentleman yields back.

2850 Mr. Pallone. Mr. Chairman.

2851 Mr. Burgess. The chair would ask is there an amendment on
2852 the bill?

2853 Mr. Pallone. Mr. Chairman, I believe Mr. Cardenas has one

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2854 but he is not here. I mean, I will be prepared to offer it, if
2855 that is okay.

2856 Mr. Burgess. The clerk will report the amendment.

2857 Mr. Pallone. It is technical.

2858 The Clerk. Amendment to H.R. 1925.

2859 [The amendment of Mr. Cardenas follows:]

2860

2861 ***** COMMITTEE INSERT 29 *****

2862 Mr. Burgess. Reading of the amendment is dispensed with.
2863 And the gentleman is recognized for five minutes on the amendment.

2864 Mr. Pallone. I don't, unless you have a problem, my
2865 understanding is it is a technical amendment and I don't really
2866 have anything to add. I would urge that we support it.

2867 But I do have a comment on the underlying bill. But so does
2868 Ms. Eshoo.

2869 But as far as the amendment, I would just ask that it be moved
2870 as a technical amendment, Mr. Chairman.

2871 Mr. Burgess. Any other member wishing to be heard on the
2872 amendment?

2873 [No response.]

2874 Mr. Burgess. Seeing none, the vote is on the amendment to
2875 H.R. 1925.

2876 All those in favor.

2877 Mr. Pallone. On the amendment.

2878 Mr. Burgess. For what purpose does the gentlelady seek
2879 recognition?

2880 Ms. Eshoo. Move to strike the last word.

2881 Mr. Burgess. The gentlelady is recognized for five minutes.

2882 Mr. Eshoo. I think the underlying, the bill, makes sense.
2883 But my question is what does it have to do with opioids?

2884 Mr. Pallone. Would the gentlewoman yield?

2885 Mr. Eshoo. Sure.

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2886 Mr. Pallone. My understanding that studies have found that
2887 according to SAMHSA about 60 percent of juveniles in the justice
2888 system meet the criteria for substance use disorder. So what we
2889 are trying to do here is to say that if they are incarcerated and
2890 they lose their Medicaid services, that as soon as they are
2891 released they go back on Medicaid, so they don't lose the
2892 opportunity to have Medicaid to address their substance use
2893 disorder. That is pretty much what it does.

2894 Mr. Burgess. Will the gentlelady yield?

2895 Ms. Eshoo. I would be glad to.

2896 Mr. Burgess. One of the times of greatest risk for an opiate
2897 overdose is when someone has been incarcerated and released from
2898 incarceration because they then become relatively opiate naive
2899 during the time they are incarcerated and don't have the
2900 availability of opiates.

2901 So to institute that immediate return to therapy in fact can
2902 be lifesaving.

2903 And did the gentleman from Virginia wish also to be heard?
2904 Will you yield to the gentleman from Virginia?

2905 Ms. Eshoo. Just taking back my time. So, anyone that is
2906 incarcerated in the juvenile system will not lose their Medicaid
2907 coverage? Is that what this is?

2908 Mr. Burgess. Yes.

2909 Ms. Eshoo. Yield back. Thank you.

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2910 Mr. Burgess. Did the gentleman from --

2911 Mr. Griffith. If I might have a moment to speak, Mr.
2912 Chairman. Strike the last word.

2913 Mr. Burgess. The gentleman is recognized.

2914 Mr. Griffith. Mr. Chairman, I would just say so there is
2915 no misunderstanding, this definitely affects what we are talking
2916 about here today is opioids, but it affects any situation because
2917 it has been one of these little problems that we have had in the
2918 juvenile system. What happens is when they go in they get
2919 terminated, not just put in suspension.

2920 What we are doing now is we are putting them in suspension
2921 so, whatever their problem might be, when they come out of the
2922 juvenile system we get them back where they need to be so that
2923 we can make sure they are getting the medical assistance they are
2924 entitled to, instead of having to wade through the whole
2925 application process again.

2926 Mr. Pallone. May I inquire, Mr. Chairman, did we dispose
2927 of the amendment?

2928 Mr. Burgess. We are prepared to vote on the amendment before
2929 we go to the floor to vote, if that is the will of the committee.

2930 Seeing no objection, the vote then is on the amendment
2931 offered by Mr. Pallone for Mr. Cardenas.

2932 All those in favor, say aye.

2933 All those opposed, no.

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2934 The ayes appear to have it. The ayes have it.

2935 And the question is on favorably reporting H.R. 1925, as
2936 amended, to the full committee.

2937 All those in favor, say aye.

2938 All those opposed, no.

2939 The ayes appear to have it. The ayes have it. You don't
2940 wish a roll call vote. The bill is agreed to and forwarded to
2941 the committee.

2942 Again, the chair observes that there are a series of votes
2943 on the floor. We will reconvene immediately after the last vote.

2944 The chair stands in recess.

2945 [Recess.]

2946 Mr. Burgess. The subcommittee will come to order.

2947 The chair calls up H.R. 3192, Number 42 on the discussion
2948 draft list, and ask the clerk to report.

2949 [The bill follows:]

2950

2951 ***** COMMITTEE INSERT 30 *****

2952 The Clerk. H.R. 3192, to amend Title XXI of the Social
2953 Security Act to ensure access to mental health services for
2954 children under the Children's Health Insurance Program, and for
2955 other purposes.

2956 Mr. Burgess. Without objection, the first reading of the
2957 bill is dispensed with and the bill will be open for amendment
2958 at any point. So ordered.

2959 Are there any bipartisan amendments to the bill?

2960 [No response.]

2961 Mr. Burgess. Are there any amendments?

2962 [No response.]

2963 Mr. Burgess. Does any member wish to be recognized on the
2964 bill? The gentleman from Massachusetts seeks recognition for
2965 what purpose?

2966 Mr. Kennedy. Move to strike the last word for 30 seconds.

2967 Mr. Burgess. The gentleman is recognized for five minutes.

2968 Mr. Kennedy. Thank you, Mr. Chairman. Thank you for
2969 including this bill in this package as the CHIP Mental health
2970 Parity Act.

2971 This bill has come before this committee on a number of times
2972 through legislative process and legislative hearings. The
2973 reality of this, it seeks to close a small gap that still exists.
2974 The vast majority of CHIP plans already cover mental behavioral
2975 health. However, according to MACPAC there is a small number of

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2976 plans that do not.

2977 As we have seen an increasing prevalence of young babies born
2978 with congenital absence and illnesses, obviously a critical
2979 issue. This bill seeks to make sure that that coverage loophole
2980 is closed and that all babies get access to the care that they
2981 need.

2982 That is the hope. It is bipartisan, it is bicameral, and
2983 it costs nothing.

2984 With that, I yield back.

2985 Mr. Burgess. The chair thanks the gentleman.

2986 Other members seeking recognition on the bill? I recognize
2987 myself for five minutes.

2988 Just make the observation that the commitment was made to
2989 the gentleman when we worked on the state Children's Health
2990 Insurance reauthorization which this was something that we would
2991 take up. And today we are. So I am happy to report that.

2992 And I will yield back my time.

2993 Any other member wishing to be heard? The gentleman from
2994 North Carolina.

2995 Mr. Hudson. Thank you, Mr. Chairman.

2996 And I will move to strike the last word. I just would like
2997 to speak in favor of Mr. Kennedy's amendment.

2998 Mr. Burgess. The gentleman is recognized.

2999 Mr. Hudson. This is something we have worked on together.

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3000 And I would just urge my colleagues to support the amendment.

3001 Thank you.

3002 I yield back.

3003 Mr. Burgess. The gentleman yields back. The chair thanks
3004 the gentleman.

3005 Others? No. Seeing no other members wishing to be heard
3006 on the bill, the question now occurs on forwarding H.R. 3192 to
3007 the full committee.

3008 All those in favor, say aye.

3009 All those opposed, no.

3010 The ayes appear to have it. The ayes have it. And the bill
3011 is agreed to and forwarded to the committee.

3012 The chair calls up committee print entitled Incentives to
3013 Create Medicaid Health Homes to Treat Substance Use Disorder,
3014 Number 51 on the notice list. And ask the clerk to report.

3015 [The information follows:]

3016

3017 ***** COMMITTEE INSERT 31 *****

3018 The Clerk. Discussion draft. To amendment Title XIX of the
3019 Social Security Act to provide for an extension of the enhanced
3020 FMAP for certain Medicaid health homes for individuals with
3021 substance use disorders.

3022 Mr. Burgess. Without objection, the first reading of the
3023 bill is dispensed with. And the bill is open for amendment at
3024 any point. So ordered.

3025 Are there any bipartisan amendments to the bill?

3026 [No response.]

3027 Mr. Burgess. Any amendments to the bill?

3028 [No response.]

3029 Mr. Burgess. The chair would recognize himself for five
3030 minutes to speak on the bill. Mr. Lance is not here.

3031 Under this bill a state can receive an additional year of
3032 enhanced funding should they choose to start a substance use
3033 disorder health home. This means that if a state does not
3034 currently have a health home it can start a substance use disorder
3035 health home and receive a total of 3 years of enhanced match for
3036 the care and coordination of services that the health home
3037 provides.

3038 States that currently serve Medicaid patients with substance
3039 use disorder in either a chronic conditions health home or a severe
3040 mental illness health home would have to start a new substance
3041 use disorder health home to get the extra year of funding.

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3042 Additionally, the enhanced funding would not be available for
3043 substance use disorder patients in another health home. The
3044 funding would only be applicable to services rendered to the
3045 newly-enrolled patients with substance use disorder.

3046 This bill adds new reporting requirements that will allow
3047 the Center for Medicare and Medicaid services and stakeholders
3048 to review the effectiveness of the substance use disorder health
3049 homes. The requirements are:

3050 The quality of healthcare provided to individuals in the
3051 health homes;

3052 The access individuals in the health homes have to care;

3053 The total expenditures for individuals in health homes.

3054 The bill requires the Center for Medicare and Medicaid
3055 Services to publish the best practices for designing and
3056 implementing substance use disorder focused health homes by 1
3057 October, 2020.

3058 And I will be happy to yield to any other member. If not,
3059 I will yield back my time. Does any other member seek
3060 recognition?

3061 For what purpose does the gentleman from New Jersey seek
3062 recognition?

3063 Mr. Pallone. To strike the last word in support of the bill.

3064 Mr. Burgess. The gentleman is recognized for five minutes.

3065 Mr. Pallone. Mr. Chairman, I support the discussion draft.

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3066 Under current law, Medicaid health homes can be targeted under
3067 current law to substance use disorder, and states receive 90
3068 percent match for the first eight quarters of the health home model
3069 for special tier coordination and health management services.
3070 And the discussion draft contemplates adding an additional four
3071 quarters of the enhanced match for SUD-specific health homes.

3072 The model has been successful. By better coordinating care
3073 and linking people who need the services. Health homes are
3074 designed to improve healthcare quality and reduce costs.

3075 And in my home state we run numerous and successful
3076 behavioral health homes. So this bill is just another example
3077 of a tangible step that we can take to concretely increase the
3078 services available to those most in need. And I would urge
3079 support.

3080 I yield back to you.

3081 Mr. Burgess. The chair thanks the gentleman. The
3082 gentleman yield back.

3083 Other members wishing to be heard?

3084 [No response.]

3085 Mr. Burgess. Seeing none, the question now occurs on
3086 forwarding the committee print to the full committee.

3087 All those in favor, say aye.

3088 All those opposed, no.

3089 The ayes appear to have it. The ayes have it. And the bill

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3090 is agreed to.

3091 The chair calls up committee print entitled Medicaid IMD
3092 Additional Info Act, 52 on the list, and asks the clerk to report.

3093 [The information follows:]

3094

3095 ***** COMMITTEE INSERT 32 *****

3096 The Clerk. Discussion draft. To require the Medicaid and
3097 CHIP Payment and Access Commission to conduct a study and report
3098 on requirements applicable to and practices of institutions for
3099 mental health disease under the Medicaid program.

3100 Mr. Burgess. Without objection, the first reading of the
3101 bill is dispensed with and the bill will be open for amendment
3102 at any point. So ordered.

3103 Are there any --

3104 Mr. Upton. Mr. Chairman.

3105 Mr. Burgess. -- bipartisan amendments to the bill? For
3106 what purpose does the gentleman wish to be recognized?

3107 Mr. Upton. Strike the last word.

3108 Mr. Burgess. The gentleman is recognized for five minutes.

3109 Mr. Upton. Mr. Chairman, this is, I want to assure my
3110 colleagues that this is a noncontroversial bill. It briefly
3111 requires that Medicaid and CHIP payments and Access Commission
3112 to report no later than January 1, 2020, to submit a report on
3113 information about services furnished to Medicare enrollees who
3114 are patients in an institute of mental disease, IMD.

3115 And GAO produced a study on IMD services a couple years ago.
3116 But the goal of this legislation is to identify the gaps in our
3117 knowledge and leverage MACPAC's research capabilities to help
3118 address these gaps. And I can't imagine that there is any
3119 disagreement on this.

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3120 And I yield back my time.

3121 Mr. Burgess. The chair thanks the gentleman. The
3122 gentleman yields back.

3123 Are there any other members wishing to be heard on this?

3124 [No response.]

3125 Mr. Burgess. Seeing none, the question now occurs on
3126 forwarding the committee print to the full committee.

3127 All those in favor, say aye.

3128 All those opposed, no.

3129 The ayes appear to have it. The ayes have it. And the bill
3130 is agreed to.

3131 The chair calls up the committee print entitled Require
3132 Medicaid Programs to Report on All Core Behavioral Health
3133 Measures, Number 55 on the list, and ask the clerk to report.

3134 [The information follows:]

3135

3136 ***** COMMITTEE INSERT 33 *****

3137 The Clerk. Discussion draft. To amend Title XI of the
3138 Social Security Act to require states to annually report on
3139 certain adult health quality measures, and for other purposes.

3140 Mr. Burgess. Without objection, the first reading of the
3141 bill is dispensed with. And the bill is open for amendment at
3142 any point. So ordered.

3143 Are there bipartisan amendments to the bill?

3144 [No response.]

3145 Mr. Burgess. Are there any amendments to the bill?

3146 [No response.]

3147 Mr. Burgess. Any member wish to be heard on the bill?

3148 Mr. Guthrie. Mr. Chairman.

3149 Ms. Castor. Mr. Chairman.

3150 Mr. Burgess. For what purpose does the gentleman from
3151 Kentucky seek recognition?

3152 Mr. Guthrie. Strike the last word.

3153 Mr. Burgess. The gentleman is recognized for five minutes.

3154 Mr. Guthrie. I want to speak in support of the bill to
3155 require states to report behavioral health measures. This bill
3156 requires states to submit the measures each year. This bill will
3157 improve transparency, accountability, and will help to up quality
3158 in Medicaid behavioral health.

3159 I yield back. Does anyone yield time, but I yield back.

3160 Mr. Burgess. The chair thanks the gentleman. The

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3161 gentleman yields back.

3162 Other members wishing to be heard on the bill? For what
3163 purpose does the gentlady from Florida seek recognition?

3164 Ms. Castor. Move to strike the last word.

3165 Mr. Burgess. The gentlady is recognized for five minutes.

3166 Ms. Castor. I just wanted to note this might be the third
3167 or fourth in a row that is one of the bills that it hasn't even
3168 been introduced to the House and we are sitting here in a committee
3169 markup. And there is just a huge disconnect.

3170 And some of these I guess they might be positive. But this,
3171 this process is really doing a disservice to our ability to address
3172 the opioid epidemic at the scale it needs to be addressed. And
3173 it highlights the issue again here, we are tinkering around the
3174 edges. We are not confronting this public health crisis.

3175 We now have more, we have reached a point -- and I think I
3176 have said this before -- we have reached a point in America where
3177 we have more deaths, tens of thousands of deaths per year that
3178 is about at the scale of the peak of the HIV/AIDS epidemic. And
3179 Congress was criticized at that point for acting too slowly and
3180 not in a robust fashion. And we need to move on this. And I am
3181 afraid this is going to set us back as we continue to tinker around
3182 the edges and not really address the scale of the issue for
3183 families.

3184 I know we all feel passionately about this, but we have got

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3185 to act seriously and with a sense of urgency. And we can't wait
3186 a few more weeks. I don't think we can. I think we should, we
3187 should begin to discuss how we provide that consistent,
3188 dependable, robust funding to communities and families that is
3189 at the scale of the epidemic that faces us.

3190 And I yield back. Thank you.

3191 Mr. Burgess. The chair thanks the gentlelady.

3192 Other members wishing to be heard on the bill?

3193 [No response.]

3194 Mr. Burgess. Seeing none, the question then occurs on
3195 forwarding the committee print to the full committee.

3196 All those in favor, say aye.

3197 All those opposed, no.

3198 The ayes appear to have it. The ayes have it. And the bill
3199 is agreed to.

3200 The chair calls up committee print entitled Human Capital
3201 in Medicaid Act, Number 54 on the list, and ask the clerk to report.

3202 [The information follows:]

3203

3204 ***** COMMITTEE INSERT 34 *****

3205 The Clerk. Discussion draft. To amend Title XIX of the
3206 Social Security Act to provide for an increased federal medical
3207 assistance percentage for the compensation of qualified officers
3208 of state agencies, and for other purposes.

3209 Mr. Burgess. Without objection, the first reading of the
3210 bill is dispensed with, and the bill is open for amendment at any
3211 point. So ordered.

3212 Are there any bipartisan amendments to the bill?

3213 [No response.]

3214 Mr. Burgess. Any amendments to the bill?

3215 [No response.]

3216 Mr. Burgess. Any member wish to be heard on the bill? For
3217 what purpose does the gentleman from Kentucky --

3218 Mr. Guthrie. Mr. Chairman, I move to strike the last word.

3219 Mr. Burgess. The gentleman is recognized for five minutes.

3220 Mr. Guthrie. Thank you, Mr. Chairman.

3221 While the opioid crisis presents Medicaid directors with a
3222 challenge that is large in scope, it is just one of the challenges
3223 Medicaid leaders face. And states need to be equipped with the
3224 best Medicaid leaders possible. Yet, states struggle to hire and
3225 retain high caliber Medicaid leaders, which is why I urge
3226 bipartisan support for the Helping Unite Managers who have
3227 Abilities with Novel Chances to Activate the Possibilities of
3228 Innovation, Transformation, and Leadership in Medicaid Act.

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3229 This bill provides enhanced federal medical assistance
3230 percentage to use towards recruit and retain talented leaders with
3231 specific expertise and capabilities.

3232 I yield back my time.

3233 Mr. Burgess. The chair thanks the gentleman. The
3234 gentleman yields back.

3235 Other members seeking time on the bill?

3236 [No response.]

3237 Mr. Burgess. Seeing none --

3238 Mr. Pallone. Mr. Chairman. Can I strike the last word, Mr.
3239 Chairman?

3240 Mr. Burgess. The gentleman is recognized for five minutes.

3241 Mr. Pallone. I just wanted to say that paying our
3242 hard-working state Medicaid agency workers is nothing anyone is
3243 against. However, we do have limited funds and we should be
3244 putting any money we have towards treatment for people with SUD.
3245 And state Medicaid infrastructure issues may be an issue, but that
3246 is not the issue we are here to vote on today.

3247 So I do urge my colleagues to vote no on this bill.

3248 Mr. Burgess. Does the gentleman yield back?

3249 Mr. Pallone. Wants the time, but yes.

3250 Mr. Burgess. The chair thanks the gentleman. The
3251 gentleman yields back.

3252 Did I hear another question on our side?

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3253 [No response.]

3254 Mr. Burgess. The question now occurs on forwarding the
3255 committee print to the full committee.

3256 All those in favor, say -- or do you wish a recorded vote?

3257 Mr. Pallone. Recorded vote, Mr. Chairman.

3258 Mr. Burgess. A recorded vote is requested. The clerk will
3259 call the roll.

3260 The Clerk. Mr. Guthrie?

3261 Mr. Guthrie. Aye.

3262 The Clerk. Mr. Guthrie votes aye.

3263 Mr. Barton?

3264 [No response.]

3265 The Clerk. Mr. Upton?

3266 Mr. Upton. Aye.

3267 The Clerk. Mr. Upton votes aye.

3268 Mr. Shimkus?

3269 Mr. Shimkus. Aye.

3270 The Clerk. Mr. Shimkus votes aye.

3271 Mrs. Blackburn?

3272 Mrs. Blackburn. Aye.

3273 The Clerk. Mrs. Blackburn votes aye.

3274 Mr. Latta?

3275 [No response.]

3276 The Clerk. Mrs. McMorris Rodgers?

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3277 [No response.]

3278 The Clerk. Mr. Lance.

3279 Mr. Lance. Aye.

3280 The Clerk. Mr. Lance votes aye.

3281 Mr. Griffith?

3282 Mr. Griffith. Aye.

3283 The Clerk. Mr. Griffith votes aye.

3284 Mr. Bilirakis?

3285 Mr. Bilirakis. Aye.

3286 The Clerk. Mr. Bilirakis votes aye.

3287 Mr. Long?

3288 Mr. Long. Aye.

3289 The Clerk. Mr. Long votes aye.

3290 Mr. Bucshon?

3291 Mr. Bucshon. Aye.

3292 The Clerk. Mr. Bucshon votes aye.

3293 Mrs. Brooks.

3294 Mrs. Brooks. Aye.

3295 The Clerk. Mrs. Brooks votes aye.

3296 Mr. Mullin?

3297 [No response.]

3298 The Clerk. Mr. Hudson?

3299 Mr. Hudson. Aye.

3300 The Clerk. Mr. Hudson votes aye.

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3301 Mr. Collins?

3302 Mr. Collins. Aye.

3303 The Clerk. Mr. Collins votes aye.

3304 Mr. Carter?

3305 Mr. Carter. Aye.

3306 The Clerk. Mr. Carter votes aye.

3307 Chairman Walden?

3308 The Chairman. Aye.

3309 The Clerk. Chairman Walden votes aye.

3310 Mr. Green?

3311 Mr. Green. No.

3312 The Clerk. Mr. Green votes no.

3313 Mr. Engel?

3314 [No response.]

3315 The Clerk. Ms. Schakowsky?

3316 Ms. Schakowsky. No.

3317 The Clerk. Ms. Schakowsky votes no.

3318 Mr. Butterfield?

3319 Mr. Butterfield. No.

3320 The Clerk. Mr. Butterfield votes no.

3321 Ms. Matsui?

3322 Ms. Matsui. No.

3323 The Clerk. Ms. Matsui votes no.

3324 Ms. Castor?

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3325 Ms. Castor. No.

3326 The Clerk. Ms. Castor votes no.

3327 Mr. Sarbanes?

3328 Mr. Sarbanes. No.

3329 The Clerk. Mr. Sarbanes votes no.

3330 Mr. Lujan?

3331 Mr. Lujan. No.

3332 The Clerk. Mr. Lujan votes no.

3333 Mr. Schrader?

3334 Mr. Schrader. No.

3335 The Clerk. Mr. Schrader votes no.

3336 Mr. Kennedy?

3337 Mr. Kennedy. No.

3338 The Clerk. Mr. Kennedy votes no.

3339 Mr. Cardenas?

3340 [No response.]

3341 The Clerk. Ms. Eshoo?

3342 Ms. Eshoo. No.

3343 The Clerk. Ms. Eshoo votes no.

3344 Ms. DeGette?

3345 Ms. DeGette. No.

3346 The Clerk. Ms. DeGette votes no.

3347 Mr. Pallone?

3348 Mr. Pallone. No.

3349 The Clerk. Mr. Pallone votes no.
3350 Chairman Burgess?
3351 Mr. Burgess. Aye.
3352 The Clerk. Chairman Burgess votes aye.
3353 Mr. Burgess. May I ask how the gentleman from Ohio, Mr.
3354 Latta, is recorded?
3355 Mr. Latta. Aye.
3356 The Clerk. Mr. Latta votes aye.
3357 Mr. Burgess. Other members seeking to be recorded? Has it
3358 been 34 seconds yet, because Mr. Barton says it takes him 34
3359 seconds to walk down here. Aha.
3360 How is Mr. Mullin recorded?
3361 Mr. Barton. Aye.
3362 Mr. Burgess. It's a good yes.
3363 The Clerk. Mr. Barton votes aye.
3364 Mr. Burgess. The gentleman from Oklahoma?
3365 The Clerk. Mr. Mullin.
3366 Mr. Mullin. Aye.
3367 The Clerk. Mr. Mullin votes aye.
3368 Mr. Burgess. Other members seeking? Has Mr. Engel been
3369 recorded?
3370 The clerk will report.
3371 The Clerk. Mr. Chairman, on that vote there were 18 ayes
3372 and 12 nays.

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3373 Mr. Burgess. Eighteen ayes and 12 nays, the committee print
3374 is agreed to and forwarded to the full committee.

3375 The chair calls up committee print entitled Medicaid
3376 Pharmaceutical Home Act, Number 48 on the list, and asks the clerk
3377 to report.

3378 [The information follows:]

3379

3380 ***** COMMITTEE INSERT 35 *****

3381 The Clerk. Discussion draft. To amend Title XIX of the
3382 Social Security Act to require states to operate drug management
3383 programs for at-risk beneficiaries, and for other purposes.

3384 Mr. Burgess. Without objection, the first reading of the
3385 bill is dispensed with. The bill is open for amendment at any
3386 point.

3387 Are there any bipartisan amendments to the bill?

3388 [No response.]

3389 Mr. Burgess. Are there any amendments to the bill?

3390 [No response.]

3391 Mr. Burgess. Does any member seek recognition to speak on
3392 the bill? For what purpose does the gentleman from Florida seek
3393 recognition?

3394 Mr. Bilirakis. I ask to strike the last word, Mr. Chairman.

3395 Mr. Burgess. The gentleman is recognized for five minutes.

3396 Mr. Bilirakis. Thank you, Mr. Chairman.

3397 The discussion draft of the Medicaid Pharmaceutical Home Act
3398 would codify the lock-in program with Medicaid and require it in
3399 all 50 states and territories. Patient review and restriction
3400 programs are a common tool to address the opioid crisis. These
3401 programs, often called lock-in, directly address the problem of
3402 drug diversion, or doctor shopping, or pharmacy shopping by
3403 locking a patient to a single designated provider, pharmacy, or
3404 both.

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3405 This successful tool has been utilized in Tricare and
3406 commercial insurance. The opioid crisis is taking a heavy toll
3407 across America, as you know, but it is an even heavier toll on
3408 Medicaid beneficiaries who are more likely to both be addicted
3409 to opioids and to overdose on them, unfortunately.

3410 According to the Kaiser Family Foundation, about 38 percent
3411 of opioid-dependent non-elderly adults, about 2 million people,
3412 are insured by Medicaid. This means that Medicaid covers 4 in
3413 10 non-elderly adults with an opioid addiction.

3414 In North Carolina, one report found that while the Medicaid
3415 population represented approximately 20 percent of the state
3416 population in 2007, it experienced one-third of the unintentional
3417 overdose deaths.

3418 In 2013, the Trust for America's Health issued a report on
3419 strategies to stop the prescription drug epidemic. And Number
3420 11 was Medicaid lock-in. They wrote, and I quote, "In order to
3421 help healthcare providers monitor potential abuse or
3422 inappropriate utilization of controlled prescription drugs,
3423 states have implemented programs requiring high users of certain
3424 drugs to use only one pharmacy and get prescriptions for
3425 controlled substances from only one medical office."

3426 I continue to quote. "The lock-in programs can help avoid
3427 doctor shopping while ensuring appropriate pain care for
3428 patients."

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3429 The formula that every state uses is different and varies.
3430 At the last opioid hearing, witnesses talked about how their
3431 Medicaid plans provide lock-in programs. Centene operates a
3432 Medicaid managed care plan -- it is a managed care plan in the
3433 State of Florida -- and testified to their lock-in program.

3434 And I quote, "In Florida you have to have three
3435 prescriptions, three providers, and three different settings and
3436 claims within the last 180 days. Lock-in allows you for, one,
3437 an integrated care plan to be developed for an individual; two,
3438 it eliminates a lot of kinds of drug-seeking behavior," again this
3439 is under the Medicaid program, and then "three, it allows for a
3440 kind of transition beyond managing the pills themselves but
3441 actually helping the individual to get social support services
3442 and treatment and recovery services afterwards." So very
3443 important.

3444 So, again, both Centene and Magellan testified about how
3445 effective lock-in has been in state Medicaid programs in reducing
3446 utilization and hospital admissions. But one thing that they
3447 mentioned is that Medicaid is fundamentally different than
3448 Medicare. We know that. We have one Medicare program but we have
3449 50 Medicaid programs. Every Medicaid program is different and
3450 build to fit the needs of their states. And we have to include
3451 the territories as well.

3452 We can't do a one-size-fits-all approach for lock-in. I

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3453 think most of you would agree. This discussion draft for the
3454 Medicaid Pharmaceutical Home Act tries to strike the right balance
3455 to bring some uniformity to the Medicaid lock-in program while
3456 allowing states the flexibility to decide to design it to fit their
3457 own needs.

3458 The bill would also require several reports from CMS and
3459 MACPAC on lock-in, and also establish some best practices so that
3460 states can improve their programs and improve outcomes for their
3461 populations.

3462 Again, I think this is a good bill. And I look forward to
3463 advancing this bill to the full committee level.

3464 I yield back, Mr. Chairman. Thank you.

3465 Mr. Green. Mr. Chairman.

3466 Mr. Burgess. The chair thanks the gentleman.

3467 Mr. Green. Strike the last word.

3468 Mr. Burgess. The gentleman is recognized for five minutes.

3469 Mr. Green. Thank you, Mr. Chairman.

3470 This policy would require all states to have a lock-in
3471 program that identifies at-risk Medicaid beneficiaries based on
3472 certain criteria, and sets limits on the number of prescribers
3473 and dispensers they may utilize, whether under a fee-for-service
3474 of managed care arrangement.

3475 There are issues in this legislation that could impede
3476 beneficiary access or interfere with what states do already.

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3477 While Medicaid lock-in programs are a tool that state Medicaid
3478 programs already use to track concerning opioid practices, this
3479 legislation goes beyond simply requiring state Medicaid programs
3480 to run a lock-in program by putting in place a federal standard
3481 for the first time in Medicaid for such programs.

3482 While this is not necessarily a bad thing conceptually, the
3483 language here is simply not in place yet where I can support the
3484 bill. There are still many consequences for beneficiaries with
3485 respect to appeals and how this bill could either define a
3486 beneficiary for purposes of the program. The language may also
3487 interfere with how many of our states already run these programs.
3488 For instance, the bill has taken away some of the appeals rights
3489 that beneficiaries have today in many state lock-in programs.

3490 We also need to ensure that Medicaid lock-in fully aligns
3491 with Medicare lock-in where it is applicable. Put simply, we need
3492 to take more time with this bill before I can feel comfortable
3493 for voting in favor.

3494 And I yield back my time.

3495 Mr. Pallone. Will the gentleman yield?

3496 Mr. Green. I will be glad to yield to my ranking member.

3497 Mr. Pallone. Thank you. I just want to say that I
3498 appreciate Mr. Bilirakis' trying to improve the underlying bill.
3499 And he does to some extent. But it is still a major problem and,
3500 you know, I want to express some of my concerns.

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3501 We have before us a bill that would require all state Medicaid
3502 programs to have a lock-in program for at-risk Medicaid
3503 beneficiaries and gets for the first time a federal standard for
3504 such a program. But I have concerns that the legislation as
3505 drafted sets the wrong federal standard and could impede
3506 beneficiary access to care and interfere with what states do
3507 already.

3508 So, for example, in my home state of New Jersey we ensure
3509 that beneficiaries have a choice as to what pharmacy and
3510 prescribers they are assigned to. And that kind of a policy is
3511 not part of this legislation.

3512 We also have to be sure that we are targeting the right
3513 beneficiaries for a lock-in program based on evidence-based
3514 standards, and that our beneficiaries have clear appeals rights,
3515 and that states have a defined process for ongoing review for
3516 whether a beneficiary needs to remain in the program.

3517 These are all components of the Medicare lock-in program
3518 established by this committee just two years ago. And Medicaid
3519 beneficiaries deserve the same level of consideration. And the
3520 programs should be aligned, I am talking between Medicare and
3521 Medicaid.

3522 If we are going to set a federal standard that has such a
3523 direct beneficiary impact, it must be the right one. We worked
3524 for months, years even, on Medicare lock-in, and I think Medicaid

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3525 is even doubly complicated because near all states are operating
3526 a lock-in program already.

3527 So, again, this is a perfect example of where, you know,
3528 lock-ins make sense. But you have got to get it right. You
3529 shouldn't have different ones for Medicare and Medicaid in my
3530 opinion, and you have got to be conscious of what states are
3531 already doing. And I just don't think that this legislation, even
3532 with the amendment, accomplishes that goal.

3533 So, again, I would ask that, you know, that my colleagues
3534 vote no on this. And, hopefully, as we go to full committee we
3535 can address some of these concerns.

3536 I yield back to Mr. Green.

3537 Mr. Green. And I yield back my time, Mr. Chairman.

3538 Mr. Burgess. The chair thanks the gentleman. The
3539 gentleman yields back.

3540 For what purpose does the gentleman from Oregon seek
3541 recognition?

3542 The Chairman. To strike the last word.

3543 Mr. Burgess. The gentleman is recognized for five minutes.

3544 The Chairman. Mr. Chairman, I am going to support this. I
3545 think it makes a lot of sense. We are obviously open to working
3546 with our colleagues on both sides of the aisle on these discussion
3547 drafts. That is why they are discussion drafts at this point.

3548 And I think on the issue of lock-in we had some pretty good

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3549 testimony along the way from some of our witnesses about how
3550 effective these programs have been. You know, we asked the
3551 Congressional Research Service to do a literature review to see
3552 if there were any published studies that demonstrate that
3553 beneficiaries are harmed by lock-in programs. They didn't find
3554 that.

3555 There is an appeals process for beneficiaries who are
3556 identified at risk. Forty-eight states have some form of a
3557 lock-in program. This policy targets lock-in for just controlled
3558 substances only. It directs states to use a beneficiaries
3559 health-care history and geography to assign providers and
3560 pharmacies and allow beneficiaries to appeal if they want to
3561 change their assigned providers and dispensers.

3562 You know, this is one of those issues that keeps being brought
3563 our way at the roundtables I have done in my district, at the
3564 hearings we have had before this subcommittee that there are
3565 people, tragically, that are gaming the system, that are getting
3566 access to multiple pharmacies and prescriptions. And it is
3567 leading to illicit drugs on the black market. It is leading to
3568 overdose deaths.

3569 My numbers were a little off earlier today. It is 4.8 people
3570 per hour are dying, but 1,000 a day go into overdose issues in
3571 emergency rooms. I think this is a solid, thoughtful piece of
3572 reform that will make a difference. It is proven to work where

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3573 it is in place today. We want uniformity around the country.
3574 And, obviously, we would work with people as this goes to full
3575 committee in good faith. And we would hope that my colleagues
3576 on the other side of the aisle would support this and work with
3577 us as we deal with these issues.

3578 With that, Mr. Chair, I yield back.

3579 Mr. Burgess. Does the gentleman from Florida -- will the
3580 gentleman from Oregon yield to the gentleman from Florida?

3581 The Chairman. I would be delighted to yield to the gentleman
3582 from Florida before I yield back.

3583 Mr. Bilirakis. Thank you, Mr. Chairman.

3584 And I would like to say that in my opinion we have plenty
3585 of flexibility in the bill for the states. However, willing to
3586 work with the other side on this particular bill to get it right.
3587 I want you all to be, obviously, comfortable with the bill. But
3588 I think it is so very important, it will save lives.

3589 And, again, you know, people that need help have to get help.
3590 And with this lock-in program I think we will accomplish that.

3591 So I appreciate that and I yield back. And I would love to
3592 see a favorable vote, bipartisan vote on this particular bill.
3593 Thank you.

3594 Mr. Burgess. The chair thanks the gentleman. The
3595 gentleman yields back.

3596 Other members wish to be heard on the bill?

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3597 [No response.]

3598 Mr. Burgess. Seeing none, the question now occurs on
3599 favorable forwarding --

3600 Mr. Pallone. I would ask for a recorded vote, Mr. Chairman.

3601 Mr. Burgess. -- of the committee print to the full
3602 committee.

3603 A recorded vote is requested. The clerk will call the roll.

3604 The Clerk. Mr. Guthrie?

3605 Mr. Guthrie. Aye.

3606 The Clerk. Mr. Guthrie votes aye.

3607 Mr. Barton?

3608 [No response.]

3609 The Clerk. Mr. Upton?

3610 Mr. Upton. Aye.

3611 The Clerk. Mr. Upton votes aye.

3612 Mr. Shimkus?

3613 Mr. Shimkus. Aye.

3614 The Clerk. Mr. Shimkus votes aye.

3615 Mrs. Blackburn?

3616 Mrs. Blackburn. Aye.

3617 The Clerk. Mrs. Blackburn votes aye.

3618 Mr. Latta?

3619 Mr. Latta. Aye.

3620 The Clerk. Mr. Latta votes aye.

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3621 Mrs. McMorris Rodgers?
3622 [No response.]
3623 The Clerk. Mr. Lance.
3624 Mr. Lance. Aye.
3625 The Clerk. Mr. Lance votes aye.
3626 Mr. Griffith?
3627 Mr. Griffith. Aye.
3628 The Clerk. Mr. Griffith votes aye.
3629 Mr. Bilirakis?
3630 Mr. Bilirakis. Aye.
3631 The Clerk. Mr. Bilirakis votes aye.
3632 Mr. Long?
3633 Mr. Long. Aye.
3634 The Clerk. Mr. Long votes aye.
3635 Mr. Bucshon?
3636 Mr. Bucshon. Aye.
3637 The Clerk. Mr. Bucshon votes aye.
3638 Mrs. Brooks.
3639 Mrs. Brooks. Aye.
3640 The Clerk. Mrs. Brooks votes aye.
3641 Mr. Mullin?
3642 Mr. Mullin. Aye.
3643 The Clerk. Mr. Mullin votes aye.
3644 Mr. Hudson?

3645 Mr. Hudson. Aye.

3646 The Clerk. Mr. Hudson votes aye.

3647 Mr. Collins?

3648 Mr. Collins. Aye.

3649 The Clerk. Mr. Collins votes aye.

3650 Mr. Carter?

3651 Mr. Carter. Aye.

3652 The Clerk. Mr. Carter votes aye.

3653 Chairman Walden?

3654 The Chairman. Aye.

3655 The Clerk. Chairman Walden votes aye.

3656 Mr. Green?

3657 Mr. Green. No.

3658 The Clerk. Mr. Green votes no.

3659 Mr. Engel?

3660 Mr. Engel. No.

3661 The Clerk. Mr. Engel votes no.

3662 Ms. Schakowsky?

3663 Ms. Schakowsky. No.

3664 The Clerk. Ms. Schakowsky votes no.

3665 Mr. Butterfield?

3666 Mr. Butterfield. No.

3667 The Clerk. Mr. Butterfield votes no.

3668 Ms. Matsui?

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3669 Ms. Matsui. No.
3670 The Clerk. Ms. Matsui votes no.
3671 Ms. Castor?
3672 Ms. Castor. No.
3673 The Clerk. Ms. Castor votes no.
3674 Mr. Sarbanes?
3675 Mr. Sarbanes. No.
3676 The Clerk. Mr. Sarbanes votes no.
3677 Mr. Lujan?
3678 Mr. Lujan. No.
3679 The Clerk. Mr. Lujan votes no.
3680 Mr. Schrader?
3681 Mr. Schrader. No.
3682 The Clerk. Mr. Schrader votes no.
3683 Mr. Kennedy?
3684 Mr. Kennedy. No.
3685 The Clerk. Mr. Kennedy votes no.
3686 Mr. Cardenas?
3687 Mr. Cardenas. No.
3688 The Clerk. Mr. Cardenas votes no.
3689 Ms. Eshoo?
3690 Ms. Eshoo. No.
3691 The Clerk. Ms. Eshoo votes no.
3692 Ms. DeGette?

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3693 Ms. DeGette. No.

3694 The Clerk. Ms. DeGette votes no.

3695 Mr. Pallone?

3696 Mr. Pallone. No.

3697 The Clerk. Mr. Pallone votes no.

3698 Chairman Burgess?

3699 Mr. Burgess. Aye.

3700 The Clerk. Chairman Burgess votes aye.

3701 Mr. Barton?

3702 Mr. Barton. Aye.

3703 The Clerk. Mr. Barton votes aye.

3704 Mr. Burgess. Are there other members wishing to be

3705 recorded?

3706 [No response.]

3707 Mr. Burgess. The clerk will report.

3708 The Clerk. Mr. Chairman, on that vote there were 18 ayes

3709 and 14 nays.

3710 Mr. Burgess. Eighteen ayes and 14 nays, the bill is -- the

3711 committee print is agreed to and forwarded to the full committee.

3712 I am advised that there is a recess that is going to be called

3713 for one hour. And the committee stands in recess and will

3714 reconvene at 6:15 p.m. Eastern time.

3715 [Recess.]

3716 Mr. Burgess. I will call the subcommittee back to order.

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3717 And the chair calls up Committee Print entitled, Limited Repeal
3718 of the IMD Exclusion for Adult Medicaid Beneficiaries with
3719 Substance Use Disorder, Number 47 on the list, and ask the Clerk
3720 to report.

3721 [The information follows:]

3722

3723 ***** COMMITTEE INSERT 36 *****

3724 The Clerk. Discussion draft to amend Title XIX of the Social
3725 Security Act to allow states to provide under Medicaid services
3726 for certain individuals with substance use disorders in
3727 institutions for mental diseases.

3728 Mr. Burgess. Without objection, the first reading of the
3729 bill is dispensed with, and the bill is open for amendment at any
3730 point, so ordered. Are there any bipartisan amendments to the
3731 bill?

3732 Are there any amendments to the bill?

3733 Does any member wish to be heard on the bill?

3734 For what purpose does the gentleman from Oregon seek
3735 recognition?

3736 The Chairman. To strike the last word, Mr. Chairman.

3737 Mr. Burgess. The gentleman is recognized for 5 minutes.

3738 The Chairman. Mr. Chairman, we have heard a lot from,
3739 frankly, people at home, people I have met with just recently,
3740 here today, from the National Association for Behavioral Health
3741 and their members out in Oregon and elsewhere about this issue
3742 of IMD. And I want to quote from the NABH letter that they sent
3743 to you and Mr. Green where they say, since 1965, the IMD exclusion
3744 has prohibited federal payments to states for services of adult
3745 Medicaid beneficiaries between the ages of 21 and 64 who are
3746 treated in facilities that have more than 16 beds and that provide
3747 inpatient or residential behavioral health, substance use

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3748 disorders, SUD, and mental illness treatment.

3749 Two federal commissions, one nonpartisan, the other
3750 bipartisan, along with a growing number of governors, Medicaid
3751 directors, judges, district attorneys, law enforcement officers,
3752 mental health and substance use treatment advocates, and
3753 healthcare providers and professionals are calling on Congress
3754 to provide states relief from the IMD exclusion.

3755 We appreciate that you and your committee are acting on this
3756 urgent issue. States need relief from the IMD exclusion and the
3757 Energy and Commerce Committee's legislative language provides
3758 that relief for SUD treatment, close quote.

3759 I think that says a lot about what we are trying to do here.
3760 The discussion draft allows state Medicaid programs, from fiscal
3761 year 2019 through 2023, to remove the IMD exclusion for Medicaid
3762 beneficiaries age 21 to 64 with substance use disorder. Medicaid
3763 then could pay for up to 90 days total of care in the IMD during
3764 a 12-month period. Beneficiaries would need to be assessed after
3765 the first 30 days to determine if continued care is appropriate
3766 and medically necessary for the next 60 days.

3767 Now the legislation also requires states to maintain at least
3768 the number of licensed beds at institutions for mental diseases
3769 owned, operated, or contracted for by the state that were being
3770 maintained as of the date of the enactment of that subsection in
3771 the bill, if higher as of the date, if the state applies to the

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3772 secretary to include such medical assistance under the state plan
3773 amendment pursuant to this subsection. So we have a maintenance
3774 of effort in here to make sure that services in the help of mental
3775 disease continue with a maintenance of effort among the states.

3776 Then we also worked with our colleagues across the aisle to
3777 make sure we have continuity of care. So it maintains at least
3778 the level of funding expended by the state and political
3779 subdivisions thereof, other than under Medicaid, from non-federal
3780 funds for, one, inpatient services in an institution for mental
3781 diseases and for active psychiatric care and treatment provided
3782 on an outpatient basis.

3783 Now this level of funding may not be less than the level of
3784 such funding for such services and care as of the date of enactment
3785 of the policy so we have a maintenance of effort, we have a
3786 continuum of care requirement, but most importantly we are
3787 expanding essentially needed help and care for those with
3788 substance use disorder. Now states can go through a waiver
3789 process today, but it doesn't give them the certainty and clarity
3790 and direction that we are able to give them through this discussion
3791 draft moving forward.

3792 As I say, the National Association for Behavioral
3793 Healthcare, the letter that they sent to you, Mr. Chairman, to
3794 Mr. Green, call on us to do this. They very much support the
3795 language we have put forward. We are listening to those on the

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3796 front lines of taking care of this vulnerable population, and I
3797 would urge my colleagues to support approval of sending this bill
3798 on to the full committee.

3799 And with that unless anyone wants the rest of my time, I would
3800 turn to the gentlelady from Tennessee, Mrs. Blackburn.

3801 Mrs. Blackburn. Thank you, Mr. Chairman. And hearing from
3802 my constituents in Tennessee who provide care and are always
3803 looking to make beds available for those that need care, they are
3804 so supportive of this legislation. One of the provisions that
3805 they point to regularly and a point that they make is there is
3806 no such thing as a one-size-fits-all treatment for those with
3807 substance abuse disorders and behavioral health disorders. And
3808 if we are looking for a way to increase access to badly needed
3809 treatment and care, this is a very appropriate step for us to take.

3810 And with that I yield back to the chair.

3811 The Chairman. And I thank the gentlelady for yielding back.
3812 You know, I would also point out that public health experts,
3813 providers, policymakers of both parties, have expressed problems
3814 with the current IMD barrier to care.

3815 The American Hospital Association said, in part, this
3816 initiative is more urgent than ever given the shortage of beds
3817 available to treat patients with opioid disorder. The National
3818 Association of Psychiatric Health Systems has said the IMD
3819 exclusion is an outdated provisional law. The Treatment Advocacy

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3820 Center has said that despite a nationwide shortage of psychiatric
3821 treatment beds that has reached crisis proportion, the IMD
3822 exclusion stands in the way of facilities providing desperately
3823 needed care, making it illegal for facilities to receive federal
3824 reimbursement for treating Medicaid recipients with serious
3825 medical illness.

3826 The National Alliance on Mental Illness has said that it supports
3827 modifying this federal law known as the IMD exclusion to allow
3828 Medicaid to pay for short-term stays of adults 21 to 64 in
3829 psychiatric hospitals and facilities.

3830 This is the kind of care that our fellow citizens, our
3831 neighbors, our friends are crying out for and it is up to us to
3832 change a law that was well-intended when passed but way before
3833 this opioid epidemic has swept the country and destroyed the lives
3834 of our fellow citizens.

3835 And so, Mr. Chairman, I would urge support for this very
3836 thoughtful, well-supported, well-rounded piece of legislation.
3837 I yield back.

3838 Mr. Burgess. The chair thanks the gentleman. The
3839 gentleman yields back. Are there other members wishing to be
3840 heard?

3841 For what purpose does the gentleman from New Jersey seek --

3842 Mr. Pallone. I strike the last word in opposition.

3843 Mr. Burgess. The gentleman is recognized for 5 minutes.

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3844 Mr. Pallone. Thank you, Mr. Chairman.

3845 I can't support the legislation in its current form and I
3846 had heard from the disability community and others which has made
3847 me come to this conclusion. Obviously we need all the tools
3848 available to address the opioid crisis. Inpatient treatment
3849 centers that focus on the treatment of behavioral health needs
3850 are undisputedly part of that and we need to do what we can to
3851 ease access to care. And so I do support the CMS guidance, both
3852 the guidance from the Obama and Trump administrations that allow
3853 states to waive the IMD exclusion if the state also takes steps
3854 to ensure that people with SUDs have access to other care they
3855 need including preventive treatment and recovery services.

3856 And so far, 21 states have waivers approved or pending before
3857 the administration and I think these waivers are important to
3858 support. That is why I also support legislation before the
3859 committee that would help states expand provider treatment
3860 capacity across the continuum of care to help states meet their
3861 SUD waiver requirements, and I also support doing whatever we can
3862 to make it easier for states to apply for SUD waivers.

3863 My home state of New Jersey, for example, has approval for
3864 a waiver right now. Under that New Jersey waiver they have total
3865 flexibility. For example, they could provide as many or as little
3866 inpatient days in an IMD as are needed, and New Jersey has
3867 committed to larger milestones to redesign their full system and

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3868 build out all SUDs benefits. So this flexibility makes sense.
3869 I think the administration's policy to allow for IMD reimbursement
3870 while also incentivizing states to expand community treatment
3871 options is a good one.

3872 And while we focus a lot on inpatient treatment and we should,
3873 it is important to note that MACPAC has also found that state
3874 Medicaid programs have significant gaps in outpatient treatment.
3875 MACPAC has found that most states have gaps in substance use
3876 disorder, SUD, coverage, covering an average just six of nine
3877 services described by the American Society of Addiction Medicine
3878 as necessary to address the continuum of care.

3879 And we heard in our legislative hearing on this issue that
3880 we can't push a system where people cycle in and out of
3881 institutions. People with substance use disorders need a range
3882 of supports to be well long term. Unfortunately, I am still
3883 concerned about how the language in this bill, also a 5-year policy
3884 but a state option with more restrictions and waivers, fits in
3885 with our 1115 waivers that more than 20 states have already
3886 invested in.

3887 I am mostly concerned that the bill lacks the incentives the
3888 waivers provide from approving the full continuum of care for
3889 people with SUDs and could instead push to overinvest in IMDs
3890 relative to community-based SUD services. So rather than
3891 offering states flexibility to invest in the services their

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3892 communities need, I am concerned that this bill would require
3893 states to increase their investment in IMD services to access
3894 federal funds. And also, while we do not have a score as of yet,
3895 I have to believe that this bill is by far and away the most costly
3896 before us and we have not yet had a discussion about offsets.

3897 So just let me be clear, Mr. Chairman. Cutting Medicaid
3898 benefits or eligibility for the very people that need care makes
3899 no sense and I will not agree to it. Medicaid health coverage
3900 is critical and we need to make sure the program is there for
3901 everyone that needs care. So in the short time this legislation
3902 has been publicly available, stakeholders have weighed in
3903 vehemently on both sides of the particulars of the bill and I think
3904 for that reason we need to work additional, we have to spend more
3905 time with our stakeholders before we should support this
3906 legislation.

3907 I just think the bill is too important to get wrong. I
3908 understand what you are trying to do. I understand what the
3909 chairman of the full committee said. But I just think that this
3910 is not the right way to go about it. We can get there but we are
3911 not there yet. So I would ask my colleagues to oppose it, and
3912 I would -- I don't know if anybody wants my minute. They can get
3913 their own time. I yield back.

3914 Mr. Burgess. The gentleman yields back. The chair thanks
3915 the gentleman.

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3916 The gentleman from New Jersey, for what purpose do you seek
3917 recognition?

3918 Mr. Lance. Yes, Mr. Chairman. I yield to the chairman of
3919 the full committee.

3920 The Chairman. And I thank the gentleman from New Jersey.
3921 I appreciate the other gentleman from New Jersey's comments and
3922 would hope that rather than vote against this he would work with
3923 us. That is why it is in discussion draft. But let me just say
3924 that again the National Association for Behavioral Healthcare,
3925 the people in the front lines of this fight, said about this
3926 legislation and about this whole issue that recent reports have
3927 asserted that the existing 1115 SUD waiver option provides
3928 sufficient relief from the IMD and that the repeal is not
3929 necessary.

3930 While SUD waivers are helpful they are far from perfect. Too
3931 often advocates against repealing the IMD fail to consider the
3932 following important points. Number one, according to MACPAC, and
3933 I know the gentleman referenced MACPAC, but they actually say and
3934 I quote, Section 1115 waivers are not a viable option for all
3935 states, close quote.

3936 Two, it can take years for the Centers for Medicare and
3937 Medicaid Services, CMS, to approve 1115 waivers and it may require
3938 additional time for new state laws to implement the waiver and
3939 a longer time for a new state regulatory structure to implement

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3940 the waiver. Three, 1115 waivers can be terminated and future
3941 administrations can take away or refuse to extend waivers. And
3942 four, waivers do not address the underlying statutory
3943 discrimination of the IMD which blocks access to critical levels
3944 of care for certain patient populations.

3945 Waivers are not a solution to a bad law. Those are not my
3946 words, those are the words from the National Association for
3947 Behavioral Health. And by the way, the draft of this legislation
3948 has been available since we had our Medicaid and Medicare hearing
3949 about 2 weeks ago and so we have actually gotten a lot of good
3950 input on it. There have been changes made reflecting concerns
3951 that were raised. I think we have a very good product going
3952 forward and we believe it is in a place where while it will cost
3953 additional resources it is a manageable cost.

3954 And so I would hope that my colleagues would work with us
3955 as been discussed on these discussion drafts going forward and
3956 not simply vote against them. And so I really think that in the
3957 middle of the opioid crisis it is important for states to leverage
3958 all available tools to combat this epidemic.

3959 And so with that I would yield to the gentleman from Kentucky,
3960 Mr. Guthrie, I believe, was seeking some time.

3961 Mr. Guthrie. Well, thank you. You actually answered. You
3962 addressed what I was going to talk about.

3963 The Chairman. All right, the gentleman from New Jersey.

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3964 Mr. Pallone. Don't misunderstand me, I think that this can
3965 be corrected. But I think it is also important for us to vote
3966 no because, you know, what we have in front of us is not acceptable.
3967 So, you know, just because we are saying that we want to -- look,
3968 almost every one of the bills that we have today that I am saying
3969 that we oppose or that I oppose, you know, if you make some major
3970 changes, maybe not all of them but in a lot of cases we could
3971 support them or I could support them.

3972 But I think it is important for us to point out as we are
3973 that, you know, that right now these bills that we are not
3974 supporting don't meet the test. And, you know, as I have said
3975 before I would rather that we held the bill and try to correct
3976 rather than ask us to vote for it in the current form. That is
3977 all I wanted to say, Mr. Chairman.

3978 The Chairman. I yield back to the gentleman from New Jersey,
3979 Mr. Lance.

3980 Mr. Lance. And I yield back.

3981 Mr. Burgess. The gentleman yields back and the chair thanks
3982 the gentleman. Are there other members seeking to be heard?

3983 For what purpose does the gentlelady from Illinois seek
3984 recognition?

3985 Ms. Schakowsky. Thank you, Mr. Chairman. I move to strike
3986 the last word.

3987 Mr. Burgess. The lady is recognized for 5 minutes.

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3988 Ms. Schakowsky. So, you know, I want to say to the chairman
3989 of the full committee, this is my 20th year here. This idea of
3990 working together usually happens before we pass a bill out of
3991 subcommittee. So I am opposing this bill because I think we
3992 should not be locking states into their current spending levels
3993 for institutions for mental disease, IMD, and psychiatric care
3994 without letting states take into account the need for other
3995 services.

3996 Under this bill, if a state needed to adjust its spending
3997 because its residents need more home and community-based care,
3998 it would be barred from doing so within the money that they are
3999 obligated to spend on the same services. The array of services
4000 people with substance abuse disorder need goes well beyond care
4001 in an IMD. They often need ongoing, and you know this, ongoing
4002 community-based services such as case management, medication
4003 assisted treatment, and peer support services.

4004 So, sometimes states need the ability to shift these services
4005 and their budgets as their residents need them. As someone exits
4006 residential treatment, there has to be services in place to help
4007 them maintain their recovery, prevent relapses, help them quickly
4008 return to treatment if relapses occur. So over time as more
4009 people are in recovery and fewer people need inpatient care, then
4010 states wouldn't be able to shift their spending to the services
4011 that are needed to support the residents with SUD.

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4012 So, currently, states have the flexibility to increase
4013 funding for beds under guidance from the Obama and Trump
4014 administrations but only as part of a continuum of care. This
4015 guidance includes a full range of preventive treatment and
4016 recovery services provided in accordance with evidence-based
4017 standards. Ten states have SUD waivers. And I know you said that
4018 sometimes they are hard to get. So maybe we can work on this
4019 together to come up with a bill that works for all the states.

4020 This bill is opposed by the National Health Law Program, the
4021 Center on Budget and Policy Priorities, and the Bazelon Center
4022 for Mental Health Law. And so, you know, I am not necessarily
4023 against this, but really I don't understand the idea where we pass
4024 something out of committee that has barely been vetted, and so
4025 I am a no vote.

4026 The Chairman. Will the gentlelady yield?

4027 Ms. Schakowsky. Sure.

4028 The Chairman. Will the gentlelady yield, because as fate
4029 would have it we have both been here 20 years or 19. I think I
4030 was like '98 and I think you were as well or thereabouts.

4031 Ms. Schakowsky. '98, we are in the same class.

4032 The Chairman. Yes. And so I guess I have a different
4033 recollection, which is it was kind of common practice to have a
4034 discussion draft in sub, agree to work together on the way to full.
4035 And so where we have reached agreement there are bills and where

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4036 we still have issues to work out in good faith we are prepared
4037 to do that going forward.

4038 And in terms of the issue raised, because they are legitimate
4039 issues, the waivers lock you in for 5 years as well. This is a
4040 state-planned option not a requirement or a mandate. It is for
4041 5 years. But what we have heard from the American Hospital
4042 Association, the National Association of Psychiatric Health
4043 Systems, the Treatment Advocacy Center, the National Alliance on
4044 Mental Illness, is the IMD is outdated, constrictive in this era
4045 we are in with opioid addiction and abuse, and they are desperate
4046 to get this kind of additional help available as an option not
4047 a mandate. And we would actually step up and help pay for it
4048 through Medicaid from the federal government.

4049 Ms. Schakowsky. Let me just say about waivers, if I could.

4050 The Chairman. Yes.

4051 Ms. Schakowsky. The waivers do not lock in a spending level.
4052 You say for 5 years, but it does not lock in. States could still
4053 have the flexibility in terms of moving money around to meet the
4054 needs at the moment.

4055 The Chairman. Well, part of what we are trying to do here
4056 is make sure they are not playing a shell game too and take away
4057 from mental health services. So that is why you have a
4058 continuation of effort requirement here. This is about if we are
4059 going to give you more support we expect it to go to help people

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4060 with substance abuse disorder, substance use disorder.

4061 Ms. Schakowsky. To one thing not necessarily then if they
4062 want to shift to community-based care, to home care, to other kinds
4063 of services.

4064 The Chairman. That is just in this bill. I mean we are
4065 doing a lot of other things through the money through the omnibus
4066 and other appropriations we have put forward. I am not
4067 diminishing the other needs. But in this particular bill we are
4068 dealing specifically with the Medicaid population and the IMD
4069 restriction, trying to get a new set of flexibility that can't
4070 be jerked back by the next administration or this administration.

4071 You know, the waivers come and the waivers go and it doesn't
4072 give them certainty. This would give them certainty for beds that
4073 may be available but can't be used that are in desperate need by
4074 people who have this addiction and need this help. And so I
4075 realize we have some disagreements.

4076 Ms. Schakowsky. Okay, I am going to reclaim my time.

4077 The Chairman. Yes. We would be happy to work with you going
4078 to full.

4079 Ms. Schakowsky. Okay, thank you.

4080 Mr. Burgess. Expired. For what purpose does the gentleman
4081 from Oregon seek recognition?

4082 Mr. Schrader. I would yield some time to the ranking member.

4083 Mr. Burgess. The gentleman is recognized to strike the last

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4084 word for 5 minutes.

4085 Mr. Pallone. And I thank the gentleman from Oregon. You
4086 know, I don't want to belabor this, but look, the problem that
4087 we have today is that we have all these discussion drafts which,
4088 you know, myself and others feel on this side are kind of
4089 half-baked to say the least.

4090 And that is why, you know, you can't really ask us to say
4091 okay, we are going to work with you, let's go to full committee,
4092 because we just feel that many of these bills, you know, haven't
4093 been introduced. They don't have a number. We haven't had a lot
4094 of time to look at them. They haven't had much technical
4095 assistance. And so I think it is just unfair. I mean not that
4096 it matters, ultimately, but, you know, because we are going to
4097 do what we want to do, but I just think you have to understand
4098 why we can't just say, you know, vote for these things and say
4099 we will fix them later. They are just too, they are in too
4100 preliminary of form. They are too half baked, you know, there
4101 just hasn't been enough time to look at them.

4102 So all these concerns that we have I think necessitate a lot
4103 more study and we just can't say, okay, we will figure this out
4104 in full committee, Mr. Chairman. I don't want to belabor the
4105 point, but I just want to make it clear why today is a little bit
4106 different.

4107 The Chairman. Would the gentleman yield just on one point?

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4108 Mr. Pallone. Sure. Who am I yielding to?

4109 Mr. Burgess. The chairman of the full committee.

4110 The Chairman. Me down here on the end.

4111 Mr. Pallone. The gentleman from Oregon, yes.

4112 The Chairman. The other gentleman from Oregon. My staff
4113 tells me we have technical assistance on every Medicaid bill put
4114 forth.

4115 Mr. Pallone. In many cases -- reclaiming my time -- it has
4116 only been available for the last couple days or the last week.
4117 Not to mention the fact that this administration isn't the best
4118 in that regard to begin with, but go ahead. I yield back. I mean
4119 yield back to you.

4120 The Chairman. I have nothing to add.

4121 Mr. Pallone. All right.

4122 Oh, you want time too? Go ahead.

4123 Mr. Burgess. The chair would just add, the observation I
4124 recall --

4125 Mr. Pallone. I yield to the gentleman from Texas.

4126 Mr. Burgess. I recall a late night when the now ranking
4127 member of the full committee was chairman of the subcommittee and
4128 brought what was called the CLASS Act to the dais very late at
4129 night, never been vetted, never been evaluated, and it was in fact
4130 sort of adopted by the full committee as a draft at that point
4131 and sent on to the Senate. So it does happen, just an observation.

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4132 Mr. Pallone. No, I understand. And I still maintain that
4133 the CLASS Act was a good bill and I am not happy with the previous
4134 President for having decided against it. It was also part of the
4135 legacy of Senator Ted Kennedy and I think we should have proceeded
4136 with it --

4137 Mr. Kennedy. Which I agree.

4138 Mr. Pallone. -- but that is another day, and for another
4139 day.

4140 Mr. Burgess. For another day.

4141 Mr. Pallone. I yield back.

4142 Mr. Burgess. The gentleman yields back.

4143 Seeing no other members seeking to be heard on the bill, the
4144 question now occurs on forwarding the Committee Print to the full
4145 committee.

4146 Mr. Pallone. Chairman, I am asking for a roll call on this.

4147 Mr. Burgess. The gentleman requests a recorded vote. The
4148 Clerk will call the roll.

4149 The Clerk. Mr. Guthrie?

4150 Mr. Guthrie. Aye.

4151 The Clerk. Mr. Guthrie votes aye.

4152 Mr. Barton?

4153 Mr. Upton?

4154 Mr. Shimkus?

4155 Mrs. Blackburn?

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4156 Mrs. Blackburn. Aye.

4157 The Clerk. Mrs. Blackburn votes aye.

4158 Mr. Latta?

4159 Mr. Latta. Aye.

4160 The Clerk. Mr. Latta votes aye.

4161 Mrs. McMorris Rodgers?

4162 Mr. Lance?

4163 Mr. Lance. Aye.

4164 The Clerk. Mr. Lance votes aye.

4165 Mr. Griffith?

4166 Mr. Griffith. Aye.

4167 The Clerk. Mr. Griffith votes aye.

4168 Mr. Bilirakis?

4169 Mr. Bilirakis. Aye.

4170 The Clerk. Mr. Bilirakis votes aye.

4171 Mr. Long?

4172 Mr. Long. Aye.

4173 The Clerk. Mr. Long votes aye.

4174 Mr. Bucshon?

4175 Mr. Bucshon. Aye.

4176 The Clerk. Mr. Bucshon votes aye.

4177 Mrs. Brooks?

4178 Mrs. Brooks. Aye.

4179 The Clerk. Mrs. Brooks votes aye.

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4180 Mr. Mullin?
4181 Mr. Mullin. Aye.
4182 The Clerk. Mr. Mullin votes aye.
4183 Mr. Hudson?
4184 Mr. Collins?
4185 Mr. Collins. Aye.
4186 The Clerk. Mr. Collins votes aye.
4187 Mr. Carter?
4188 Mr. Carter. Aye.
4189 The Clerk. Mr. Carter votes aye.
4190 Chairman Walden?
4191 The Chairman. Aye.
4192 The Clerk. Chairman Walden votes aye.
4193 Mr. Green?
4194 Mr. Engel?
4195 Ms. Schakowsky?
4196 Ms. Schakowsky. No.
4197 The Clerk. Ms. Schakowsky votes no.
4198 Mr. Butterfield?
4199 Mr. Butterfield. No.
4200 The Clerk. Mr. Butterfield votes no.
4201 Ms. Matsui?
4202 Ms. Matsui. No.
4203 The Clerk. Ms. Matsui votes no.

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4204 Ms. Castor?
4205 Ms. Castor. No.
4206 The Clerk. Ms. Castor votes no.
4207 Mr. Sarbanes?
4208 Mr. Sarbanes. No.
4209 The Clerk. Mr. Sarbanes votes no.
4210 Mr. Lujan?
4211 Mr. Lujan. No.
4212 The Clerk. Mr. Lujan votes no.
4213 Mr. Schrader?
4214 Mr. Schrader. No.
4215 The Clerk. Mr. Schrader votes no.
4216 Mr. Kennedy?
4217 Mr. Kennedy. No.
4218 The Clerk. Mr. Kennedy votes no.
4219 Mr. Cardenas?
4220 Ms. Eshoo?
4221 Ms. DeGette?
4222 Ms. DeGette. No.
4223 The Clerk. Ms. DeGette votes no.
4224 Mr. Pallone?
4225 Mr. Pallone. No.
4226 The Clerk. Mr. Pallone votes no.
4227 Chairman Burgess?

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4228 Mr. Burgess. Aye.

4229 The Clerk. Chairman Burgess votes aye.

4230 Mr. Shimkus?

4231 Mr. Shimkus. Yes.

4232 The Clerk. Mr. Shimkus votes aye.

4233 Mr. Burgess. Are there other members wishing to be

4234 recorded?

4235 The Clerk. Mr. Hudson?

4236 Mr. Hudson. Aye.

4237 The Clerk. Mr. Hudson votes aye.

4238 Mr. Burgess. The Clerk will report.

4239 The Clerk. Mr. Chairman, on that vote there were 16 ayes

4240 and 10 nays.

4241 Mr. Burgess. 16 ayes and 10 nays. The Committee Print is

4242 forwarded on to the full committee.

4243 The chair calls up Committee Print entitled Medicaid Drug

4244 Improvement Act -- this is Number 49 on the list -- and ask the

4245 Clerk to report.

4246 [The information follows:]

4247 ***** COMMITTEE INSERT 37 *****

4248 The Clerk. Discussion draft to amend Title XIX of the Social
4249 Security Act to require as a condition of receipt of full federal
4250 medical assistance percentage under Medicaid that state Medicaid
4251 plans have in place certain drug utilization review activities.

4252 Mr. Burgess. Without objection, the first reading of the
4253 bill is dispensed with. The bill is open for amendment at any
4254 point, so ordered. Are there any bipartisan amendments to the
4255 bill?

4256 Are there any amendments to the bill?

4257 Does any member wish to be heard on the bill?

4258 For what purpose does the gentlelady from Tennessee seek
4259 recognition?

4260 Mrs. Blackburn. Thank you, Mr. Chairman.

4261 Mr. Burgess. The gentlelady is recognized for 5 minutes.

4262 Mrs. Blackburn. And thank you, Mr. Chairman. This is in
4263 the form of a discussion draft, but this is an issue and a bill
4264 that I discussed with Kim Brandt from CMS at our last hearing and
4265 we talked about the way some states are using medical management
4266 tools and techniques to address the opioid crisis for Medicaid
4267 enrollees.

4268 And I mentioned Tennessee, my state, and TennCare, our
4269 Medicaid delivery program, had recently implemented new policies
4270 and including a 5-day limit on initial prescriptions for acute
4271 pain, prior authorization for refills and a robust pharmacy

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4272 lock-in program, and many of these programs have been positive.
4273 They are having good outcomes for enrollees, but not every state
4274 has put these tools and these techniques in place.

4275 So the Medicaid drug improvement act looks at states' drug
4276 utilization review or DUR programs and puts into place a minimum
4277 standard for states and their DUR programs, puts limitations in
4278 place for opioid refills to monitor concurrent prescribing of
4279 opioids and other drugs such as the benzodiazepines and the
4280 antipsychotics, to monitor the antipsychotic prescribing for
4281 children. Of course in the roundtable we did last week we heard
4282 a little bit about that, have at least one buprenorphine and
4283 naloxone combination drug on the Medicaid drug formulary.

4284 Because of the forward-looking good work already done by some
4285 of the states' Medicaid programs, this bill does not mandate
4286 specific policies or thresholds for these standards. It allows
4287 states the flexibility to determine the best approach needed for
4288 their enrollees. Requiring these minimum standards will benefit
4289 the Medicaid enrollees in every state while allowing individual
4290 states to determine the best way to implement them.

4291 And I encourage support of this bill, and if no one wants
4292 time to speak on the bill I will yield back my time.

4293 Mr. Burgess. The gentlelady yields back. The chair thanks
4294 the gentlelady. Are there other members wishing to be heard on
4295 the bill?

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4296 For what purpose does the gentleman from New Jersey seek
4297 recognition?

4298 Mr. Pallone. Strike the last word in opposition.

4299 Mr. Burgess. The gentleman is recognized for 5 minutes.

4300 Mr. Pallone. I thank you, Mr. Chairman. I know this is --

4301 Mr. Burgess. And I am going to ask the gentleman to suspend
4302 for just a second. I am having a little trouble hearing up here,
4303 so if we can keep side conversations to a minimum. Please
4304 proceed.

4305 Mr. Pallone. I agree. I agree. Thank you, Mr. Chairman.
4306 This is a complex issue area into Medicaid, the DUR, or drug
4307 utilization review. And I appreciate we have done some, a lot
4308 of work on this legislation, but again we haven't had a great deal
4309 of time to work on it. And I am certainly hopeful that the
4310 chairman and Mrs. Blackburn will continue to work with us as we
4311 move forward.

4312 But again, as it stands I am not comfortable with the bill.
4313 We are putting a new federal standard in place for Medicaid DUR
4314 programs and I just don't think we have thought enough about how
4315 we are going to do it and what the impact might be on state Medicaid
4316 programs. DUR programs are one tool that allow states to review
4317 prospectively, concurrently, and retroactively, potentially
4318 questionable drug claims and identify patterns of fraud, abuse,
4319 overuse, or medically unnecessary care, and implements corrective

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4320 action when needed. It is important that such programs be
4321 impactful and we are integrating DUR as a tool with other programs
4322 the state may have in place.

4323 But we have to make certain that with this implementation
4324 is evidence based or that the standard is evidence based at the
4325 federal level with respect to any new requirements to states, and
4326 I just don't think the language before the committee is there yet
4327 or is clear enough. I am also concerned that we need an
4328 opportunity, you know, to spend more time on this, frankly. You
4329 know, again I don't know what you have in mind in terms of these
4330 things coming before the full committee. Fortunately we have a
4331 week, but, you know, a break next week, but I am still concerned
4332 that we aren't going to have enough time.

4333 The overwhelming majority of states already have a
4334 buprenorphine naloxone drug with preferred status on their
4335 states' formulary as this bill would mandate. But I think it
4336 would be more important if you want to move the ball forward on
4337 this crisis to address prior authorization, step therapy, and
4338 lifetime limits barriers which an overwhelming majority of states
4339 also have. And I think we should be addressing the actual
4340 barriers to treatment for people and I don't think we are actually
4341 there yet.

4342 So again, I know I sound a little bureaucratic here, but I
4343 mean this is something we have got to get right and I think we

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4344 haven't done enough work on it to know what the impact is going
4345 to be on the state Medicaid program and I don't want to hurt the
4346 state Medicaid programs by putting together something that we
4347 don't really understand what the impact is going to be. So I would
4348 again urge a no vote on this, Mr. Chairman.

4349 Mr. Burgess. Would the gentleman yield?

4350 Mr. Pallone. Of course.

4351 Mr. Burgess. My understanding is we have data from at least
4352 35 states. I will agree with the ranking member, I don't like
4353 step therapy either. I think there are some things perhaps we
4354 can work on between here and full committee, but I am obviously
4355 still going to urge that we proceed with the approval of this
4356 draft.

4357 So I yield back to the gentleman who then yields back.

4358 Any other members seeking time on this bill?

4359 Seeing none, the question --

4360 Mr. Pallone. And again I would ask for a recorded vote, Mr.
4361 Chairman.

4362 Mr. Burgess. The questions then occurs on forwarding the
4363 Committee Print to the full committee. A recorded vote has been
4364 requested. The Clerk will call the roll.

4365 The Clerk. Mr. Guthrie?

4366 Mr. Guthrie. Aye.

4367 The Clerk. Mr. Guthrie votes aye.

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4368 Mr. Barton?

4369 Mr. Barton. Aye.

4370 The Clerk. Mr. Barton votes aye.

4371 Mr. Upton?

4372 Mr. Upton. Aye.

4373 The Clerk. Mr. Upton votes aye.

4374 Mr. Shimkus?

4375 Mr. Shimkus. Aye.

4376 The Clerk. Mr. Shimkus votes aye.

4377 Mrs. Blackburn?

4378 Mrs. Blackburn. Aye.

4379 The Clerk. Mrs. Blackburn votes aye.

4380 Mr. Latta?

4381 Mr. Latta. Aye.

4382 The Clerk. Mr. Latta votes aye.

4383 Mrs. McMorris Rodgers?

4384 Mr. Lance?

4385 Mr. Lance. Aye.

4386 The Clerk. Mr. Lance votes aye.

4387 Mr. Griffith?

4388 Mr. Griffith. Aye.

4389 The Clerk. Mr. Griffith votes aye.

4390 Mr. Bilirakis?

4391 Mr. Bilirakis. Aye.

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4392 The Clerk. Mr. Bilirakis votes aye.
4393 Mr. Long?
4394 Mr. Long. Aye.
4395 The Clerk. Mr. Long votes aye.
4396 Mr. Bucshon?
4397 Mr. Bucshon. Aye.
4398 The Clerk. Mr. Bucshon votes aye.
4399 Mrs. Brooks?
4400 Mr. Mullin?
4401 Mr. Mullin. Aye.
4402 The Clerk. Mr. Mullin votes aye.
4403 Mr. Hudson?
4404 Mr. Collins?
4405 Mr. Collins. Aye.
4406 The Clerk. Mr. Collins votes aye.
4407 Mr. Carter?
4408 Mr. Carter. Aye.
4409 The Clerk. Mr. Carter votes aye.
4410 Mr. Green?
4411 Chairman Walden?
4412 The Chairman. Aye.
4413 The Clerk. Chairman Walden votes aye.
4414 Mr. Engel?
4415 Ms. Schakowsky?

4416 Ms. Schakowsky. No.
4417 The Clerk. Ms. Schakowsky votes no.
4418 Mr. Butterfield?
4419 Mr. Butterfield. No.
4420 The Clerk. Mr. Butterfield votes no.
4421 Ms. Matsui?
4422 Ms. Matsui. No.
4423 The Clerk. Ms. Matsui votes no.
4424 Ms. Castor?
4425 Mr. Sarbanes?
4426 Mr. Sarbanes. No.
4427 The Clerk. Mr. Sarbanes votes no.
4428 Mr. Lujan?
4429 Mr. Lujan. No.
4430 The Clerk. Mr. Lujan votes no.
4431 Mr. Schrader?
4432 Mr. Schrader. No.
4433 The Clerk. Mr. Schrader votes no.
4434 Mr. Kennedy?
4435 Mr. Kennedy. No.
4436 The Clerk. Mr. Kennedy votes no.
4437 Mr. Cardenas?
4438 Ms. Eshoo?
4439 Ms. DeGette?

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4440 Ms. DeGette. No.

4441 The Clerk. Ms. DeGette votes no.

4442 Mr. Pallone?

4443 Mr. Pallone. No.

4444 The Clerk. Mr. Pallone votes no.

4445 Chairman Burgess?

4446 Mr. Burgess. Aye.

4447 The Clerk. Chairman Burgess votes aye.

4448 Mrs. Brooks?

4449 Mrs. Brooks. Aye.

4450 The Clerk. Mrs. Brooks votes aye.

4451 Mr. Hudson?

4452 Mr. Hudson. Aye.

4453 The Clerk. Mr. Hudson votes aye.

4454 Mr. Chairman, on that vote there were 18 ayes and 9 nays.

4455 Mr. Burgess. Do you really want to hear?

4456 The chair calls up Committee Print entitled Medicaid

4457 Partnership Act, Number 50 on the list, and ask the Clerk to

4458 report.

4459 [The information follows:]

4460

4461 ***** COMMITTEE INSERT 38 *****

4462 The Clerk. Discussion draft to amend Title XIX of the Social
4463 Security Act to provide for requirements under the Medicaid
4464 program relating to the use of qualified prescription drug
4465 monitoring programs and prescribing certain controlled
4466 substances.

4467 Mr. Burgess. Without objection, the first reading of the
4468 bill is dispensed with and the bill is open for amendment at any
4469 point, so ordered. Are there any bipartisan amendments to the
4470 bill?

4471 Are there any amendments to the bill?

4472 Does any member wish to be heard on the bill?

4473 For what purposes does the gentleman from Virginia seek
4474 recognition?

4475 Mr. Griffith. Mr. Chairman, I wish to be heard on the bill.

4476 Mr. Burgess. The gentleman is recognized for 5 minutes.

4477 Mr. Griffith. Thank you, Mr. Chairman, I appreciate it.

4478 The Partnership Act being considered today will require state
4479 Medicaid programs to integrate prescription drug monitoring data
4480 into the provider's clinical workflow and requires the provider
4481 to check the PDMP system before prescribing a controlled
4482 substance. This bill will also help increase communication among
4483 border states, reducing and hopefully eliminating the challenges
4484 some face accessing information across state lines. This has
4485 obviously been one of the issues in my district because of all

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4486 the different states that my district borders.

4487 Studies have shown that in states where the provider is
4488 required to check the PDMP before prescribing, prescriptions and
4489 doctor shopping have decreased. Mortality rates decreased as
4490 well. PDMP technology exists now that can help save lives by
4491 identifying those who may be at risk and I hope my colleagues on
4492 both sides of the aisle will work to help ensure these tools are
4493 used in a way that can make a critical difference in the fight
4494 against this epidemic.

4495 Likewise, Mr. Chairman, I have some data from SAMHSA and a
4496 report from Brandeis University that shows how effective using
4497 PDMPs can be and I would like to submit those for the record.

4498 Mr. Burgess. Without objection, so ordered.

4499 [The information follows:]

4500

4501 ***** COMMITTEE INSERT 39 *****

4502 Mr. Griffith. And with that, Mr. Chairman, I hope that we
4503 will pass this good bill on to the full committee, and I yield
4504 back for now.

4505 Mr. Burgess. The chair thanks the gentleman. The
4506 gentleman yields back. Are there other members seeking
4507 recognition?

4508 The gentleman from New Jersey recognized for 5 minutes.

4509 Mr. Pallone. Thank you, Mr. Chairman. The language in this
4510 bill is certainly better than it was and I know you, the sponsors,
4511 have taken some of our concern in effect. But I still have serious
4512 concerns with it because, first of all, I don't think Medicaid
4513 should be setting the standards for PDMPs. And the standards that
4514 would need to be effectuated, you know, outside of Medicaid's
4515 control, and our states would potentially face a penalty in their
4516 Medicaid programs and that penalty is up to the secretary so, you
4517 know, I would be concerned about what states get the penalty and
4518 which states get a pass.

4519 But, you know, mandating providers to check the PDMP in many
4520 state Medicaid programs has been met with a lot of success, but
4521 I think this bill goes beyond that and the language has more
4522 far-reaching ramifications. The privacy protections for
4523 beneficiaries, I think, are also not strong enough and the
4524 language is not quite targeted on the right goals. So again I
4525 think that, you know, the bill needs a lot more work and I am

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4526 concerned that it sets up states to take a hit on their Medicaid
4527 funding and is going to unnecessarily impact states' Medicaid
4528 funding the way it is written.

4529 So I would urge a no vote on this one as well for those
4530 reasons. I yield back.

4531 Mr. Burgess. And the gentleman yields back. Are there
4532 other members wishing to be heard on the bill?

4533 Seeing none, my preference is to vote. The question now
4534 occurs on forwarding the Committee Print. Roll call vote is
4535 requested, the Clerk will call the roll.

4536 The Clerk. Mr. Guthrie?

4537 Mr. Guthrie. Aye.

4538 The Clerk. Mr. Guthrie votes aye.

4539 Mr. Barton?

4540 Mr. Barton. Aye.

4541 The Clerk. Mr. Barton votes aye.

4542 Mr. Upton?

4543 Mr. Shimkus?

4544 Mrs. Blackburn?

4545 Mrs. Blackburn. Aye.

4546 The Clerk. Mrs. Blackburn votes aye.

4547 Mr. Latta?

4548 Mr. Latta. Aye.

4549 The Clerk. Mr. Latta votes aye.

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4550 Mrs. McMorris Rodgers?
4551 Mr. Lance?
4552 Mr. Lance. Aye.
4553 The Clerk. Mr. Lance votes aye.
4554 Mr. Griffith?
4555 Mr. Griffith. Aye.
4556 The Clerk. Mr. Griffith votes aye.
4557 Mr. Bilirakis?
4558 Mr. Bilirakis. Aye.
4559 The Clerk. Mr. Bilirakis votes aye.
4560 Mr. Long?
4561 Mr. Long. Aye.
4562 The Clerk. Mr. Long votes aye.
4563 Mr. Bucshon?
4564 Mr. Bucshon. Aye.
4565 The Clerk. Mr. Bucshon votes aye.
4566 Mrs. Brooks?
4567 Mrs. Brooks. Aye.
4568 The Clerk. Mrs. Brooks votes aye.
4569 Mr. Mullin?
4570 Mr. Mullin. Aye.
4571 The Clerk. Mr. Mullin votes aye.
4572 Mr. Hudson?
4573 Mr. Hudson. Aye.

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4574 The Clerk. Mr. Hudson votes aye.
4575 Mr. Collins?
4576 Mr. Collins. Aye.
4577 The Clerk. Mr. Collins votes aye.
4578 Mr. Carter?
4579 Mr. Carter. Aye.
4580 The Clerk. Mr. Carter votes aye.
4581 Chairman Walden?
4582 The Chairman. Aye.
4583 The Clerk. Chairman Walden votes aye.
4584 Mr. Green?
4585 Mr. Engel?
4586 Ms. Schakowsky?
4587 Ms. Schakowsky. No.
4588 The Clerk. Ms. Schakowsky votes no.
4589 Mr. Butterfield?
4590 Mr. Butterfield. No.
4591 The Clerk. Mr. Butterfield votes no.
4592 Ms. Matsui?
4593 Ms. Matsui. No.
4594 The Clerk. Ms. Matsui votes no.
4595 Ms. Castor?
4596 Mr. Sarbanes?
4597 Mr. Sarbanes. No.

4598 The Clerk. Mr. Sarbanes votes no.
4599 Mr. Lujan?
4600 Mr. Lujan. Pass.
4601 The Clerk. Mr. Lujan pass.
4602 Mr. Schrader?
4603 Mr. Schrader. No.
4604 The Clerk. Mr. Schrader votes no.
4605 Mr. Kennedy?
4606 Mr. Kennedy. No.
4607 The Clerk. Mr. Kennedy votes no.
4608 Mr. Cardenas?
4609 Ms. Eshoo?
4610 Ms. DeGette?
4611 Ms. DeGette. No.
4612 The Clerk. Ms. DeGette votes no.
4613 Mr. Pallone?
4614 Mr. Pallone. No.
4615 The Clerk. Mr. Pallone votes no.
4616 Chairman Burgess?
4617 Mr. Burgess. Aye.
4618 The Clerk. Chairman Burgess votes aye.
4619 Mr. Shimkus?
4620 Mr. Shimkus. Aye.
4621 The Clerk. Mr. Shimkus votes aye.

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4622 Mr. Upton?

4623 Mr. Upton. Aye.

4624 The Clerk. Mr. Upton votes aye.

4625 Mr. Lujan?

4626 Mr. Lujan. No.

4627 The Clerk. Mr. Lujan votes no.

4628 Mr. Burgess. Other members wishing to be recorded?

4629 Seeing none, the Clerk will report.

4630 The Clerk. Mr. Chairman, on that vote there were 18 ayes
4631 and 9 noes.

4632 Mr. Burgess. 18 ayes and 9 noes, the Medicaid Partnership
4633 Act is favorably reported to the full committee.

4634 The chair now calls up the Committee Print entitled Medicaid
4635 Graduate Medical Education Transparency Act, Number 53 on your
4636 list, and asks the Clerk to report.

4637 [The information follows:]

4638

4639 ***** COMMITTEE INSERT 40 *****

4640 The Clerk. Discussion draft to amend Title XIX of the Social
4641 Security Act to provide for reporting requirements relating to
4642 graduate medical education.

4643 Mr. Burgess. Without objection, the first reading of the
4644 bill is dispensed with and the bill is open for amendment at any
4645 point, so ordered. Are there any bipartisan amendments to the
4646 bill?

4647 Are there are any amendments to the bill?

4648 The chair would then recognize himself for 5 minutes to speak
4649 on the bill. This, I think, is one of the more important
4650 discussion drafts up for consideration today because it does deal
4651 with our physician workforce, the Graduate Medical Education
4652 Transparency Act. This draft legislation will provide Congress
4653 with more transparency about how current graduate medical
4654 education dollars are helping to equip the next generation of
4655 doctors to better identify and treat patients with substance use
4656 disorder.

4657 Medicaid is the second largest federal payer of graduate
4658 medical education and it pays about 16 percent of all GME funding.
4659 In 2015, federal agencies and state Medicaid agencies spent over
4660 \$16 billion on graduate medical education training to support
4661 direct and indirect costs of training. While the Department of
4662 Health and Human Services collects Medicaid graduate medical
4663 education expenditure information from states, there is not

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4664 enough data to help us analyze the extent to which the program
4665 is meeting the needs for the physician workforce of tomorrow.

4666 HRSA and others have noted projected shortages of physicians
4667 in coming years and there is a bipartisan interest in shoring up
4668 our healthcare workforce. Congress can pass bills that increase
4669 access to evidence-based treatment, but if you do not have the
4670 physicians equipped with the proper tools and training we will
4671 not have sufficient capacity to provide effective treatment for
4672 individuals suffering from substance use disorder.

4673 This bill seeks to address that challenge by making certain
4674 that Congress has the information needed to make thoughtful
4675 decisions in the years ahead. Some hospital stakeholders have
4676 relayed to the committee that they may have suggestions on ways
4677 to improve the language and we welcome their ideas. With more
4678 than a hundred Americans a day dying from the crisis, we have to
4679 respectfully question the defense of the status quo.

4680 I believe the epidemic calls for fresh thinking so we can
4681 better understand how federal dollars ultimately help physicians
4682 provide care for their patients. I look forward to a constructive
4683 dialogue with stakeholders that refines the language and
4684 addresses the interest of members of the committee. And I will
4685 be happy to yield to any other member who wishes time on this.
4686 If not, I will yield back and recognize the ranking member for
4687 5 minutes.

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4688 Mr. Pallone. Thank you, Mr. Chairman.

4689 This bill would require state Medicaid programs to report
4690 on a long list of measures to CMS that essentially detail how
4691 Medicaid GME funds are being used. I am not opposed to collecting
4692 data, but these are significant changes to Medicaid GME reporting
4693 and I see no reason to rush these changes through this process
4694 without adequately consulting with states on their ability to
4695 collect this information and with CMS and other stakeholders and
4696 how this information will actually help us improve GME training
4697 align with the information we collect for other forms of GME.

4698 This is really not an opioids bill. While there is obviously
4699 a need for more substance use and mental health providers, primary
4700 care and other types of providers across the country, the bill
4701 we are considering does nothing to address these physician
4702 shortages or increase treatment capacity for substance use
4703 disorders.

4704 And as I said earlier, Medicaid GME is just a small portion
4705 of our GME spending, only 16 percent overall. Asking for all this
4706 additional reporting on Medicaid GME without also considering our
4707 investments in other programs like Medicare would not provide a
4708 complete picture of physician training and it would also burden
4709 state Medicaid programs, who we know have limited resources, and
4710 potentially discourage states from using other Medicaid dollars
4711 to support GME.

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4712 It is my hope that we can work together through regular order
4713 and in collaboration with stakeholders to identify the data that
4714 is essential to collect across our GME programs and have a public
4715 discussion on how that data will help us solve the larger workforce
4716 issues we are facing. But in the short time the public has had
4717 to look at this policy, myself and others on this committee have
4718 already heard concerns from our stakeholders that this reporting
4719 would be extremely burdensome. I don't see how it helps at all
4720 with the opioid crisis. I think it is burdensome. And, you know,
4721 it is being rushed through as part of this opioid process.

4722 So I don't see any reason why this, you know, should move
4723 forward today and I would urge a no vote, Mr. Chairman. I yield
4724 back.

4725 Mr. Burgess. Will the gentleman yield?

4726 Mr. Pallone. Oh, sure.

4727 Mr. Burgess. Just for the observation that both the General
4728 Accountability Office and the Institute of Medicine recommended
4729 such data collection and that would be as part of the reason for
4730 offering this discussion draft this evening, and I yield back.

4731 Mr. Pallone. Taking back my time, I appreciate that and I
4732 am not saying that it might not be a good idea. But the problem
4733 is, it does seem like a lot of burden, again concerned about the
4734 impact on the Medicaid program, and I don't see how it has anything
4735 to do with the opioid crisis so I just don't see any reason why

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4736 we are moving this as part of this package. That is part of the
4737 concern that I have here, you know, again the test being is this
4738 going to help us with the opioid crisis and I don't see how it
4739 has anything to do with it. But in any case, I will yield back.

4740 Mr. Burgess. The chair thanks the gentleman. The
4741 gentleman yields back. Other members seeking to be heard on the
4742 bill?

4743 Is the gentleman requesting a recorded vote?

4744 Mr. Pallone. Yes.

4745 Mr. Burgess. The question now occurs on forwarding the
4746 Committee Print. The Clerk will call the roll.

4747 The Clerk. Mr. Guthrie?

4748 Mr. Guthrie. Aye.

4749 The Clerk. Mr. Guthrie votes aye.

4750 Mr. Barton?

4751 Mr. Barton. Aye.

4752 The Clerk. Mr. Barton votes aye.

4753 Mr. Upton?

4754 Mr. Shimkus?

4755 Mr. Shimkus. Aye.

4756 The Clerk. Mr. Shimkus votes aye.

4757 Mrs. Blackburn?

4758 Mrs. Blackburn. Aye.

4759 The Clerk. Mrs. Blackburn votes aye.

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4760 Mr. Latta?

4761 Mr. Latta. Aye.

4762 The Clerk. Mr. Latta votes aye.

4763 Mrs. McMorris Rodgers?

4764 Mr. Lance?

4765 Mr. Lance. Aye.

4766 The Clerk. Mr. Lance votes aye.

4767 Mr. Griffith?

4768 Mr. Griffith. Aye.

4769 The Clerk. Mr. Griffith votes aye.

4770 Mr. Bilirakis?

4771 Mr. Bilirakis. Aye.

4772 The Clerk. Mr. Bilirakis votes aye.

4773 Mr. Long?

4774 Mr. Long. Aye.

4775 The Clerk. Mr. Long votes aye.

4776 Mr. Bucshon?

4777 Mr. Bucshon. Aye.

4778 The Clerk. Mr. Bucshon votes aye.

4779 Mrs. Brooks?

4780 Mrs. Brooks. Aye.

4781 The Clerk. Mrs. Brooks votes aye.

4782 Mr. Mullin?

4783 Mr. Mullin. Aye.

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4784 The Clerk. Mr. Mullin votes aye.
4785 Mr. Hudson?
4786 Mr. Hudson. Aye.
4787 The Clerk. Mr. Hudson votes aye.
4788 Mr. Collins?
4789 Mr. Collins. Aye.
4790 The Clerk. Mr. Collins votes aye.
4791 Mr. Carter?
4792 Mr. Carter. Aye.
4793 The Clerk. Mr. Carter votes aye.
4794 Chairman Walden?
4795 The Chairman. Aye.
4796 The Clerk. Chairman Walden votes aye.
4797 Mr. Green?
4798 Mr. Engel?
4799 Ms. Schakowsky?
4800 Ms. Schakowsky. No.
4801 The Clerk. Ms. Schakowsky votes no.
4802 Mr. Butterfield?
4803 Mr. Butterfield. No.
4804 The Clerk. Mr. Butterfield votes no.
4805 Ms. Matsui?
4806 Ms. Matsui. No.
4807 The Clerk. Ms. Matsui votes no.

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4808 Ms. Castor?
4809 Ms. Castor. No.
4810 The Clerk. Ms. Castor votes no.
4811 Mr. Sarbanes?
4812 Mr. Sarbanes. No.
4813 The Clerk. Mr. Sarbanes votes no.
4814 Mr. Lujan?
4815 Mr. Lujan. No.
4816 The Clerk. Mr. Lujan votes no.
4817 Mr. Schrader?
4818 Mr. Schrader. No.
4819 The Clerk. Mr. Schrader votes no.
4820 Mr. Kennedy?
4821 Mr. Kennedy. No.
4822 The Clerk. Mr. Kennedy votes no.
4823 Mr. Cardenas?
4824 Ms. Eshoo?
4825 Ms. DeGette?
4826 Ms. DeGette. No.
4827 The Clerk. Ms. DeGette votes no.
4828 Mr. Pallone?
4829 Mr. Pallone. No.
4830 The Clerk. Mr. Pallone votes no.
4831 Chairman Burgess?

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4832 Mr. Burgess. Aye.

4833 The Clerk. Chairman Burgess votes aye.

4834 Mr. Upton?

4835 Mr. Upton. Aye.

4836 The Clerk. Mr. Upton votes aye.

4837 Mr. Burgess. And the Clerk will report.

4838 The Clerk. Mr. Chairman, on that vote there were 18 ayes
4839 and 10 noes.

4840 Mr. Burgess. 18 ayes, 10 noes, the Committee Print is agreed
4841 to and forwarded to the full committee.

4842 The chair calls up H.R. 4275 and asks the Clerk to report.

4843 [The bill follows:]

4844

4845 ***** COMMITTEE INSERT 41 *****

4846 Mr. Burgess. This is number 1 on --

4847 The Clerk. H.R. 4275, to provide for the development and
4848 dissemination of programs and materials for training pharmacists,
4849 healthcare providers, and patients on indicators that a
4850 prescription is fraudulent, forged, or otherwise indicative of
4851 abuse or diversion, and for other purposes.

4852 Mr. Burgess. Without objection, the first reading of the
4853 bill is dispensed with and the bill will be open for amendment
4854 at any point, so ordered. Are there any bipartisan amendments
4855 to the bill?

4856 Mr. Carter. Mr. Chairman, I have one.

4857 Mr. Burgess. For what purpose does the gentleman from
4858 Georgia seek recognition?

4859 Mr. Carter. Mr. Chairman, I would like to speak on the bill
4860 and then I have an amendment.

4861 [The amendment of Mr. Carter follows:]

4862

4863 ***** COMMITTEE INSERT 42 *****

4864 Mr. Burgess. The Clerk will report the amendment.

4865 The Clerk. Amendment to H.R. 4275 offered by Mr. Carter.

4866 Mr. Burgess. The gentleman is recognized for 5 minutes on
4867 his amendment.

4868 Mr. Carter. Thank you, Mr. Chairman.

4869 Mr. Chairman, deaths from drug overdose have risen in nearly
4870 every county across the United States with over 47,000 Americans
4871 being lost each year due to overdose, the equivalent of about 115
4872 people every day. More prescription opioids are being dispensed
4873 than ever before. In 2010, prescription opioid use in the U.S.
4874 translated into 693 milligrams of morphine per person, nearly
4875 doubled from 2007.

4876 This is a continuously growing problem with no simple
4877 solution. In our complex system of checks and balances, however,
4878 pharmacists are the last line of defense in the fight against
4879 prescription drug abuse. Under current law, pharmacists are
4880 required to exercise sound professional judgment when making a
4881 determination about the legitimacy of a controlled substance
4882 prescription.

4883 While the proper prescribing of controlled substances is the
4884 responsibility of the prescribing practitioner, pharmacists have
4885 a corresponding responsibility to ensure that controlled
4886 substances are only dispensed pursuant to a valid prescription
4887 issued for a legitimate medical purpose by a practitioner acting

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4888 in the usual course of his professional practice. The Empowering
4889 Pharmacists in the Fight Against Opioid Abuse Act would require
4890 the Department of Health and Human Services, the Drug Enforcement
4891 Administration, and other federal agencies responsible for
4892 combating the opioid epidemic, to produce and disseminate
4893 materials to pharmacists to provide guidance on when and how to
4894 refuse to fill a prescription that the pharmacist believes to be
4895 fraudulent

4896 I urge you to support this common-sense legislation led by
4897 myself and my colleague across the aisle, Representative
4898 DeSaulnier, that will help improve the last line of defense
4899 against prescription drug abuse in our communities.

4900 And I yield back, Mr. Chairman.

4901 Mr. Burgess. The gentleman yields back. Any other member
4902 wishing to be heard on the amendment?

4903 If not, the question occurs then on adoption of the
4904 amendment.

4905 Those in favor will say aye.

4906 Those opposed, no.

4907 The ayes appear to have it. The ayes have it.

4908 The question -- is there further discussion of the Carter
4909 bill?

4910 Mr. Lujan. Mr. Chairman?

4911 Mr. Burgess. Who seeks time? The gentleman is recognized

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4912 for 5 minutes to strike the last word.

4913 Mr. Lujan. Mr. Chairman, not necessarily a question on
4914 pertaining to the bill, I was just keeping track of the Medicaid
4915 bills that we were just on and we moved on to another block of
4916 bills. At my count there is still five Medicaid bills left. Are
4917 we going to go back to those and hear them before tonight is over?

4918 And I yield to the chairman.

4919 Mr. Burgess. We are working through at the discretion of
4920 the chair.

4921 Mr. Lujan. You are the chairman.

4922 Mr. Burgess. And we are working through at the discretion
4923 of the chair.

4924 Mr. Lujan. So that is not a yes, Mr. Chairman?

4925 Mr. Burgess. We are working through the bills.

4926 Mr. Lujan. Mr. Chairman, you know, as we talked about this
4927 evening about getting to these bills as well and the importance
4928 of hearing these bills, the majority is, if I am not mistaken they
4929 sent the order out, if you will, or the notice on these bills.
4930 They chose, you chose. The majority chose the bills that were
4931 noticed to be heard tonight and me not hearing certainty that we
4932 are going to get to the bills that were just skipped on Medicaid
4933 just causes some concern, Mr. Chairman.

4934 I certainly hope that all the bills that were noticed by the
4935 majority we are able to get back to. I don't know if there is

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4936 anything I would yield to you. But if not, I yield back the
4937 balance of my time.

4938 Mr. Burgess. We are planning on proceeding in order at the
4939 discretion of the chair.

4940 Mr. Lujan. I appreciate that, Chairman. Thank you. I
4941 look forward to hearing them.

4942 Mr. Burgess. Does the gentleman yield back?

4943 Mr. Lujan. I yield back, Mr. Chair.

4944 Mr. Burgess. Does any other member wish to be heard on the
4945 Carter bill?

4946 Seeing none, are you requesting a recorded vote?

4947 All those in favor will record by saying aye.

4948 Those opposed, no.

4949 The ayes have it and the bill is agreed to.

4950 That is at the discretion of the chair.

4951 The chair calls up H.R. 5041, Number 2 on your list, and asks
4952 the Clerk to report.

4953 [The bill follows:]

4954

4955 ***** COMMITTEE INSERT 43 *****

4956 The Clerk. H.R. 5041, to amend the Controlled Substances
4957 Act to authorize the employees of a hospice program to handle
4958 controlled substances in the residence of a deceased hospice
4959 patient to assist in disposal.

4960 Mr. Burgess. Without objection, the first reading of the
4961 bill is dispensed with. The bill is open for amendment at any
4962 point, so ordered. Are there bipartisan amendments to the bill?

4963 Are there amendments to the bill?

4964 For what purpose does the gentleman from New Jersey seek
4965 recognition?

4966 Mr. Pallone. Mr. Chairman, I have an amendment that is
4967 sponsored by Mr. Green that I would like to offer.

4968 [The amendment of Mr. Green follows:]

4969

4970 ***** COMMITTEE INSERT 44 *****

4971 Mr. Pallone. I guess it is number 2.

4972 Mr. Burgess. The Clerk will report the amendment.

4973 The Clerk. Amendment to H.R. 5041.

4974 Mr. Burgess. And the gentleman is recognized for 5 minutes
4975 on his amendment.

4976 Mr. Pallone. The legislation before us today, Mr. Chairman,
4977 which is authored by Representatives Walberg, Dingell, and
4978 Hudson, would help to reduce the number of unused controlled
4979 substances at risk of diversion or misuse by allowing hospice
4980 workers to safely dispose of these medications in the patients'
4981 homes following their passing.

4982 Today, current regulations prevent hospice personnel from
4983 handling or destroying controlled substances following a
4984 patient's passing unless the state or locality allows them to do
4985 so under law. We know that one of the major contributors to the
4986 opioid crisis today is the diversion of unused prescription
4987 opioids. It has been estimated that around 70 percent of those
4988 who abuse opioids receive them from a friend or family, making
4989 it critical that strategies be put in place that will limit the
4990 ability for leftover controlled substances to fall into the wrong
4991 hands.

4992 So Mr. Green's amendment, which I am offering, which has been
4993 drafted with input from the administration, stakeholders, and
4994 members on both sides, would make two key technical changes to

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4995 the underlying bill. First, it would require hospice personnel
4996 that will be tasked with disposing or destroying unneeded
4997 controlled substances that have they receive training through a
4998 qualified hospice program in how to properly dispose of these
4999 substances so as to prevent misuse, abuse, or diversion. If this
5000 legislation is to be successful it will be critical that hospice
5001 employees know how to dispose of controlled substances in a way
5002 that would ensure they cannot be extracted for purpose of further
5003 abuse.

5004 Secondly, the amendment would require hospice personnel to
5005 keep records on the disposal of the controlled substance including
5006 what controlled substances were destroyed as well as the time and
5007 manner in which the disposal occurred. It is my hope that this
5008 recordkeeping will help hospices to better identify if diversion
5009 or misuse may be occurring in the days following a patient's death.

5010 And again I want to thank the sponsors, Representative
5011 Walberg, Dingell, and Hudson for their work on this bill as well
5012 as the National Association for Home Care & Hospice and the
5013 National Hospice and Palliative Care Organization for their work,
5014 and I would urge members to support Mr. Green's amendment and final
5015 passage of the bill. I yield back.

5016 Mr. Burgess. The chair thanks the gentleman. The
5017 gentleman yields back. Are the other members wishing to be heard
5018 on the Green amendment?

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5019 For what purpose does the gentleman from North Carolina seek
5020 recognition?

5021 Mr. Hudson. Mr. Chairman, I would like to speak in support
5022 of the amendment offered on behalf of Mr. Green.

5023 Mr. Burgess. The gentleman is recognized for 5 minutes.

5024 Mr. Hudson. Thank you, Mr. Chairman.

5025 First, I want to thank my colleagues, Representative Tim
5026 Walberg and Representative Debbie Dingell, for their leadership
5027 on this issue. This bipartisan amendment clarifies that training
5028 will be conducted by the hospice program not the federal
5029 government.

5030 As Mr. Pallone pointed out, there are also a number of new
5031 recordkeeping requirement or there is a new recordkeeping
5032 requirement. This practical approach has hospice programs
5033 maintain records within the patient's clinical charts of the
5034 controlled substance, dosage, number of pills, and the way it was
5035 disposed. Several hospice organizations have reviewed this
5036 amendment and have indicated they believe these to be improvements
5037 to the underlying bill.

5038 I will support this amendment and urge the committee to adopt
5039 both the amendment as well as the underlying bill. And with that
5040 Mr. Chairman I will yield back.

5041 Mr. Burgess. The chair thanks the gentleman. The
5042 gentleman yields back. Are there other members wishing to be

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5043 heard on the amendment?

5044 Seeing none, the question that occurs on favorably adopting
5045 the Green amendment all those in favor will say aye.

5046 Those opposed, no.

5047 The ayes have it.

5048 The question now occurs on favorably forwarding H.R. 5041,
5049 as amended, to the full committee.

5050 All those in favor will say aye.

5051 Those opposed, no.

5052 The ayes have it and the bill is agreed to.

5053 The chair calls up H.R. 5202, Number 3 on the list, and asks
5054 the Clerk to report.

5055 [The bill follows:]

5056

5057 ***** COMMITTEE INSERT 45 *****

5058 The Clerk. H.R. 5202, to amend the Controlled Substances
5059 Act to provide for the delivery of a controlled substance by a
5060 pharmacy to an administering practitioner.

5061 Mr. Burgess. Without objection, the first reading of the
5062 bill is dispensed with and the bill will be open for amendment
5063 at any point, so ordered. Are there bipartisan amendments to the
5064 bill?

5065 Are there amendments to the bill?

5066 Does any member wish to be heard on the bill?

5067 For what purpose does the gentleman from New Jersey seek
5068 recognition?

5069 Mr. Pallone. To strike the last word in support of the bill.

5070 Mr. Burgess. The gentleman is recognized for 5 minutes.

5071 Mr. Pallone. The bill would enable controlled substances
5072 that are intended to be implanted, injected, or administered
5073 through an intrathecal pump to be dispensed directly to a
5074 healthcare practitioner for purposes of administration. The
5075 term dispense is defined in the Controlled Substances Act as the
5076 delivery of a controlled substance to an ultimate user or research
5077 subject.

5078 As the committee knows, DATA 2000 enables certain healthcare
5079 practitioners to prescribe or dispense buprenorphine in a
5080 physician's office. However, since the enactment of CSA in DATA
5081 2000, long-acting formulations of buprenorphine designed to be

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5082 injected or implemented by a healthcare practitioner have been
5083 developed and approved by the DEA. So, currently, the CSA does
5084 not contemplate the ability of a pharmacy to directly dispense
5085 a controlled substance administered by injection, implantation,
5086 or intrathecal pump to a practitioner. As a result, healthcare
5087 practitioners must purchase the medication through a buy and bill
5088 system and cover the cost of treatment in advance of any
5089 reimbursement.

5090 So this bill, authored by Representatives Costello and Rick
5091 Nolan, would allow controlled substances that are intended to be
5092 administered for purpose of maintenance or detoxification
5093 treatment by injection, implantation, or through the use of an
5094 intrathecal pump, to be dispensed by a pharmacy to a healthcare
5095 practitioner. So this change would update the CSA to acknowledge
5096 innovation in this space, help to limit the potential for
5097 diversion by allowing a pharmacy to provide them directly to the
5098 provider, and eliminate an extra step for patients who are in need
5099 of such treatment.

5100 So it is a common sense bill that will provide clarity and,
5101 more importantly, it enjoys bipartisan, bicameral support so I
5102 think it will ultimately pass and go to the President. I urge
5103 my colleagues to vote in support of it, Mr. Chairman.

5104 Mr. Burgess. The chair thanks the gentleman. The
5105 gentleman yields back.

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5106 For what purpose does the gentleman from Kentucky seek
5107 recognition?

5108 Mr. Guthrie. Strike the last word.

5109 Mr. Burgess. The gentleman is recognized for 5 minutes.

5110 Mr. Guthrie. Thank you, Mr. Chairman. The intent of this
5111 bill is to update federal law to reflect technological
5112 advancements in medicine. It is not uncommon for innovation to
5113 outpace Congress and this is the case justifying the bill before
5114 us today. The Controlled Substances Act or CSA does not account
5115 for the dispensing of injectable or intrathecal drugs. I am
5116 sorry. I was trying to pronounce that correctly.

5117 Under current law, a pharmacy cannot dispense a
5118 practitioner-administered version of buprenorphine, which is the
5119 case with new injectable forms of the treatment, since the
5120 practitioner is not the end user. What this bill clarifies is
5121 that pharmacies can dispense injectable and intrathecal
5122 controlled substances to a practitioner who administer the drug
5123 to the patient in need. Our staffs and stakeholders continue to
5124 engage with CMS and DEA to confirm this language is airtight and
5125 it is my understanding the next conversation is set to happen as
5126 soon as later this week. Quite frankly, I consider this proposal
5127 to be technical in nature and believe that it is deserving of
5128 unanimous support.

5129 And I will yield to my friend from North Carolina, Mr. Hudson.

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5130 I covered it? Okay, I covered it. I guess I covered it. So
5131 without any other taking of time, I will yield back to the chair.

5132 Mr. Burgess. The chair thanks the gentleman. The
5133 gentleman yields back. Any other member wishing to be heard on
5134 the bills?

5135 Seeing none, the question now occurs on forwarding H.R. 5202
5136 to the full committee.

5137 All those in favor say aye.

5138 Those opposed, no.

5139 The ayes have it and the bill is agreed to.

5140 The chair calls up H.R. 5483, Number 4 on the list, and asks
5141 the Clerk to report.

5142 [The bill follows:]

5143

5144 ***** COMMITTEE INSERT 46 *****

5145 The Clerk. H.R. 5483, to impose a deadline for the
5146 promulgation of interim final regulations in accordance with
5147 Section 311(h) of the Controlled Substances Act, 21 U.S. Code
5148 831(h), specifying the circumstances in which a special
5149 registration may be issued to a practitioner to engage in the
5150 practice of telemedicine, and for other purposes.

5151 Mr. Burgess. Without objection, the first reading of the
5152 bill is dispensed with. The bill is open for amendment at any
5153 point, so ordered. Are there any bipartisan amendments to the
5154 bill?

5155 Mr. Carter. Mr. Chairman, I have an amendment.

5156 [The amendment of Mr. Carter follows:]

5157

5158 ***** COMMITTEE INSERT 47 *****

5159 Mr. Burgess. For what purpose does the gentleman from
5160 Georgia seek recognition?

5161 Mr. Carter. I have an amendment at the desk and I also want
5162 to speak on the bill.

5163 Mr. Burgess. If there are no bipartisan amendments, the
5164 Clerk will report the Carter amendment.

5165 The Clerk. Amendment to H.R. 5483 offered by Mr. Carter.

5166 Mr. Burgess. And the gentleman is recognized for 5 minutes
5167 on his amendment.

5168 Mr. Carter. Thank you, Mr. Chairman.

5169 Mr. Chairman, in 2008, Congress strengthened prohibitions
5170 against distributing and dispensing controlled substances by
5171 passing the Ryan Haight Online Pharmacy Consumer Protection Act.
5172 The Ryan Haight Act made it illegal for a practitioner to dispense
5173 controlled substances through the internet without at least one
5174 in-person patient evaluation. The legislation included the
5175 ability for the Attorney General to issue a special registration
5176 to healthcare providers to prescribe controlled substances via
5177 telemedicine in legitimate emergency situations such as a lack
5178 of access to an in-person specialist.

5179 However, the waiver process has never been implemented
5180 through regulation and thus some patients still do not have the
5181 emergency access to care they need. The Special Registration for
5182 Telemedicine Clarification Act directs the Attorney General, with

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5183 the Secretary of Health and Human Services, to promulgate interim
5184 final regulations within 90 days of passage of the law. The
5185 bipartisan legislation will require the Attorney General to
5186 establish a registration process for practitioners to prescribe
5187 controlled substances using telemedicine.

5188 Sixty-two million Americans living in rural communities are
5189 more likely to be older, poorer, and suffer higher rates of chronic
5190 disease than their urban counterparts. Furthermore, a
5191 disproportionate number of Americans living in rural communities
5192 are struggling with prescription opioid abuse. I urge you to
5193 support the bipartisan legislation co-led by my colleague
5194 Representative Bustos to connect patients with the substance use
5195 disorder treatment they need without jeopardizing important
5196 safeguards to prevent misuse or diversion.

5197 Now Mr. Chairman, I would like to speak on the amendment.
5198 This amendment is being offered in response to a DEA request to
5199 lengthen the time in which they must publish rules for the
5200 establishment of the special waiver process. Under the
5201 introduced bill, DEA would have up to 90 days to complete this
5202 task. At their request, this amendment would extend this window
5203 to 1 year. I believe this is fair and it is my view that our
5204 committee should be accommodating to this minor request. Plus,
5205 finalizing rules for the special waiver process is on the unified
5206 agenda of the Justice Department and DEA, a signal that they

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5207 understand the need to implement this provision of law.

5208 With this amendment and the passage of the underlying bill,
5209 Congress will require DEA to complete this long overdue special
5210 waiver process again which they have already signaled they
5211 support. I urge your support of this amendment as well as your
5212 support of the underlying bill.

5213 Mr. Pallone. Will the gentleman yield?

5214 Mr. Guthrie. I will.

5215 Mr. Pallone. I just want to say that we support your
5216 amendment and the underlying bill. Thank you and Ms. Bustos for
5217 putting this forward because it will enable telemedicine to
5218 finally be deployed in treating patients with addiction. Thank
5219 you.

5220 Mr. Guthrie. Thank you.

5221 Mr. Burgess. Does the gentleman yield back?

5222 Mr. Guthrie. I yield back.

5223 Mr. Burgess. So the question now occurs upon the amendment
5224 to H.R. 5483. Is there any other member that wishes to speak on
5225 the amendment first?

5226 Seeing none, the question occurs on approving the amendment
5227 to H.R. 5483.

5228 All those in favor will signify by saying aye.

5229 Those opposed, no.

5230 The ayes appear to have it. The ayes have it.

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5231 Is there any other member that wishes to speak on H.R. 5483?

5232 Seeing none, the question now occurs on forwarding H.R. 5483,
5233 as amended, to the full committee. All those in favor will say
5234 aye.

5235 Those opposed, no.

5236 The ayes appear to have it and the bill is agreed to.

5237 The chair calls up the Committee Print entitled Improving
5238 Access to Remote Behavioral Health Treatment Act of 2018, Number
5239 5 on the list, and asks the Clerk to report.

5240 [The information follows:]

5241

5242 ***** COMMITTEE INSERT 48 *****

5243 The Clerk. Discussion draft to amend the Controlled
5244 Substances Act to clarify the eligibility of certain community
5245 mental health centers to register for purposes of the practice
5246 of telemedicine, and for other purposes.

5247 Mr. Burgess. Without objection, the first reading of the
5248 bill is dispensed with and the bill will be open for amendment
5249 at any point, so ordered. Are there any bipartisan amendments
5250 to the bill?

5251 Are there any amendments to the bill?

5252 Does any member seek recognition to speak on the bill?

5253 Ms. Matsui. Mr. Chairman?

5254 Mr. Burgess. Yes, the gentlelady from California, for what
5255 purpose do you seek recognition?

5256 Ms. Matsui. I move to strike the last word.

5257 Mr. Burgess. The gentlelady is recognized for 5 minutes.

5258 Ms. Matsui. Mr. Chairman, I rise in support of H.R. 5594,
5259 the Improving Access to Remove Behavioral Health Treatment Act,
5260 which I have co-authored with my colleague, Representative Gregg
5261 Harper. As we look for solutions to the opioid epidemic, one of
5262 the things we need to look at is increasing access to treatments
5263 for those suffering from substance use disorders such as opioid
5264 use disorder. Availability of treatment varies widely across the
5265 country and patients and families often don't know where to turn
5266 for evidence-based care that would really help them manage their

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5267 condition.

5268 In my district of Sacramento we have a strong network of
5269 community health clinics including behavioral health clinics.
5270 These community clinics are often the most accessible place for
5271 patients around the country to get help because the closest
5272 academic medical center with resources and expertise may be miles
5273 away. Many behavioral health clinics or mental health centers
5274 offer a wide variety of services such as acute psychiatric care,
5275 alcohol and drug services, adolescent services, peer support
5276 services, and more.

5277 They are also working more and more to integrate or
5278 coordinate with local community health clinics to ensure that the
5279 whole patient is treated both for physical and mental health
5280 conditions. However, these clinics do not always have the
5281 resources to have a full-time prescriber that is DEA licensed to
5282 prescribe controlled substances like medication assisted
5283 treatment or MAT.

5284 So when a health professional at a behavioral health clinic
5285 is seeing a patient and through the course of treatment determines
5286 that MAT may be appropriate and necessary for that patient they
5287 cannot get that care to the patient immediately, that problem can
5288 be solved using telemedicine. When a patient is at a behavioral
5289 health clinic receiving services, telemedicine could be used to
5290 bring in a DEA licensed prescriber to assess the patient and

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5291 prescribe as appropriate.

5292 Under the Ryan Haight Act, which was created to control
5293 online drug sales, there is an exception to allow for this kind
5294 of telemedicine. The exception is limited to patients who are
5295 in hospitals or clinics, but DEA doesn't currently allow community
5296 behavioral health clinics to register for the exception. This
5297 bill will simply allow community behavioral health clinics that
5298 are defined in federal law and overseen by their state to register
5299 with DEA to practice telemedicine for prescribing controlled
5300 substances.

5301 We intentionally limited the clinics we are opening this up
5302 to, to ensure that we are not giving new prescribing capability
5303 to unscrupulous actors and we specify that DEA does have the right
5304 to deny any applications if they don't deem facilities meet
5305 requirements.

5306 We are not meeting the current need for treatment for those
5307 suffering from opioid use disorder and this bill is one way to
5308 expand access to that care and help people towards long-term
5309 recovery. I urge my colleagues to support this bipartisan bill
5310 and thank you and I yield back.

5311 Mr. Burgess. Will the gentlelady yield?

5312 Ms. Matsui. Yes. Certainly I will yield.

5313 Mr. Burgess. And I want to thank you, as well as Mr. Harper
5314 who is our Oversight Subcommittee chairman, for your continued

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5315 bipartisan efforts to expand patient access through telemedicine.
5316 The two of you have been very thoughtful and pragmatic and
5317 constantly, consistently producing creative policy ideas in this
5318 space. This bill, the Improving Access to Remote Behavioral
5319 Health Treatment Act is a smart way to reach vulnerable patients
5320 who are seeking remote treatment outside of a traditional hospital
5321 or clinic setting. It is my understanding that thoughtful
5322 consideration has been given to the definition of these facilities
5323 with help of the Department of Health and Human Services and the
5324 Drug Enforcement Administration.

5325 I am glad that a bipartisan consensus was made for the
5326 purposes of this subcommittee markup and I certainly want to
5327 continue to work with both of you and other stakeholders as we
5328 move to the full committee. Again I thank the gentlelady and I
5329 will urge support of the bill. I yield back to the gentlelady.

5330 Ms. Matsui. Thank you very much, Mr. Chairman. I yield
5331 back.

5332 Mr. Burgess. The gentlelady yields back. Are there other
5333 members that wish to be heard on the bill?

5334 Seeing none, the question now occurs on forwarding the
5335 Committee Print to the full committee.

5336 All those in favor will signify by saying aye.

5337 Those opposed, no.

5338 The ayes appear to have it. The ayes have it and the bill

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5339 is agreed to.

5340 Mr. Burgess. The chair calls up the Committee Print
5341 entitled, A Bill to Amend Title XIX of the Social Security Act
5342 to Provide for Medicaid Coverage Protections for Pregnant and
5343 Postpartum Women While Receiving Inpatient Treatment for a
5344 Substance Use Disorder. This is Number 56, and I ask the Clerk
5345 to report.

5346 [The information follows:]

5347

5348 ***** COMMITTEE INSERT 49 *****

5349 The Clerk. Discussion draft to amend Title XIX of the Social
5350 Security Act to provide for Medicaid coverage protections for
5351 pregnant and postpartum women while receiving inpatient treatment
5352 for a substance use disorder.

5353 Mr. Burgess. Without objection, the first reading of the
5354 bill is dispensed with. The bill is open for amendment at any
5355 point, so ordered. Are there any bipartisan amendments to the
5356 bill?

5357 Are there any amendments to the bill?

5358 Does any member wish to be heard on the bill?

5359 For what purpose does the gentleman from New Mexico seek
5360 recognition?

5361 Mr. Lujan. Strike the last word, Mr. Chairman.

5362 Mr. Burgess. The gentleman is recognized for 5 minutes.

5363 Mr. Lujan. Thank you, Mr. Chairman.

5364 One of my top priorities is making sure that pregnant and
5365 postpartum women have what they need during this crisis. During
5366 CARE last Congress, I championed the Pregnant and Postpartum Women
5367 Act which supports facilities all over the country with the
5368 primary goal of treating mothers and their babies. I think we
5369 can all agree that we must do whatever we can for mothers and babies
5370 struggling with neonatal abstinence syndrome. If we are truly
5371 going to end this epidemic we must focus on the next generation.
5372 I believe that starts with moms and healthy pregnancies. Mothers

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5373 and babies need access to the full range of services that they
5374 are entitled to through the Medicaid program. There should be
5375 no ambiguity about the services that they deserve and have access
5376 to. Treating moms and babies together is important for
5377 struggling families. That is why this bill is important and I
5378 hope we can all work together to make it a reality.

5379 And I thank you, Mr. Chairman, and I yield back.

5380 Mr. Burgess. The chair thanks the gentleman. The
5381 gentleman yields back.

5382 For what purpose does the gentleman from Kentucky seek
5383 recognition?

5384 Mr. Guthrie. Thank you, Mr. Chairman. Oh, to strike the
5385 last word. Thank you, Mr. Chairman.

5386 Mr. Burgess. The gentleman is recognized for 5 minutes.

5387 Mr. Guthrie. Okay, thank you, Mr. Chairman. I appreciate
5388 that. I will just take a few seconds. One is that I know my
5389 friend from New Mexico has been working another bill kind of in
5390 similar in this space.

5391 I know this is a discussion draft and hasn't been introduced,
5392 but I think we can move to the full committee. We can work
5393 together in good faith and I think even though it is a discussion
5394 draft it is something I would like for my colleagues on this side
5395 of the aisle to accept. And I yield back.

5396 Mr. Lujan. Will the gentleman yield?

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5397 Mr. Guthrie. Or yield to you.

5398 Mr. Lujan. Well, Mr. Guthrie, I really appreciate that,
5399 sir, and the work that you have done in this space. Your team
5400 has been incredible and I look forward to working with you further
5401 on this, sir.

5402 Mr. Guthrie. Thank you. I yield back.

5403 Mr. Burgess. The chair thanks the gentleman. The
5404 gentleman yields back.

5405 Any other members seeking to be heard on Committee Print
5406 Number 56? If not, the question now occurs on forwarding the
5407 Committee Print to the full committee.

5408 All those in favor will signify by saying aye.

5409 Those opposed, no.

5410 The ayes appear to have it. The ayes have it and the
5411 Committee Print is forwarded to the full committee.

5412 The chair calls up H.R. 5554.

5413 [The bill follows:]

5414

5415 ***** COMMITTEE INSERT 50 *****

5416 Mr. Burgess. This is Number 58 on your list, and asks the
5417 Clerk to report.

5418 The Clerk. H.R. 5554, to amend to the Federal Food, Drug,
5419 and Cosmetic Act to reauthorize user fee programs relating to new
5420 animal drugs and generic new animal drugs.

5421 Mr. Burgess. Without objection, the first reading of the
5422 bill is dispensed with and the bill will be open for amendment
5423 at any point, so ordered. Are there bipartisan amendments to the
5424 bill?

5425 Are there amendments to the bill?

5426 For what purpose does the gentleman from Oregon seek
5427 recognition?

5428 Mr. Schrader. To talk to the bill, sir. No. Not
5429 amendment, not at this point.

5430 I guess to offer an amendment then.

5431 [The amendment of Mr. Schrader follows:]

5432

5433 ***** COMMITTEE INSERT 51 *****

5434 Mr. Burgess. The Clerk will report the Amendment.

5435 The Clerk. Amendment to H.R. 5554 offered by Mr. Schrader.

5436 Mr. Burgess. The gentleman from Oregon is recognized for
5437 5 minutes on his amendment.

5438 Mr. Schrader. Thank you. I appreciate the chair's
5439 patience. H.R. 5554 and the manager's amendment is a great
5440 bipartisan, bicameral bill to reauthorize the Animal Drug and
5441 Animal Generic Drug User Fee programs and I am glad to co-sponsor
5442 that with Mr. Mullin.

5443 As a veterinarian in rural Oregon, I am pretty familiar with
5444 the need for increased innovation in the animal drug sphere space.
5445 We don't have the breadth of clientele that our friends in the
5446 medical field do so it is tougher sometimes to get innovative drugs
5447 and different pharmaceutical companies to even play in animal
5448 veterinary medicine. My 35 years, it has been an exciting time
5449 to see what we have been able to do for our four-footed friends
5450 much like we do our two-footed friends these days.

5451 So over the past several years seeing ADUFA and AGDUFA have
5452 proved their worth, the Animal Drug User Fee program has
5453 streamlined the approval process for a lot of these
5454 pharmaceuticals, eliminated the FDA's application backlog,
5455 reduced review times, created a more predictable process, all the
5456 good things we always want to see happen. ADUFA and AGDUFA built
5457 a unique and I think very safe process to incentivize the

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5458 innovation of new animal pharmaceuticals which means better
5459 cutting edge care when our animals actually need it most. This
5460 is all to the benefit of veterinarians, companion animal owners,
5461 livestock owners, and of course animals themselves.

5462 I am glad to work with my colleague, Mr. Mullin, on this
5463 important bipartisan bill and glad to offer the manager's
5464 amendment with him and incorporate some amendments adopted by our
5465 colleagues in the Senate brings this bill closer to a bipartisan,
5466 bicameral timely passage. I urge committee support of H.R. 5554
5467 and our manager's amendment, and I yield back the balance of my
5468 time.

5469 Mr. Guthrie. [Presiding.] The gentleman yields back.

5470 Is anybody seeking recognition to discuss the amendment?

5471 Mr. Mullin from Oklahoma, you are recognized for 5 minutes.

5472 Mr. Mullin. Thank you, Mr. Chairman. And, you know, you
5473 can't have a better sponsor or a better co-sponsor of the bill
5474 than a veterinarian and the only veterinarian we have on the
5475 committee. Thank you so much for your input. I was just
5476 fortunate enough to be able to help drive the vehicle with you,
5477 but your input has been invalid. No one has more experience than
5478 you in this. Your help through this has been remarkable. The
5479 idea that we can come together and be proactive than to wait until
5480 the last minute, I think, speaks volumes. I know I personally
5481 started working on this a year ago. You have been working on this

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5482 for many years as I am sure. So we look forward to continue
5483 working this bill and making sure we can have the industry moving
5484 forward.

5485 With that, Mr. Chairman, I will yield back.

5486 Mr. Guthrie. The gentleman yields back. Is there any
5487 further discussion on the amendment?

5488 Seeing no further discussion, the question occurs on the --
5489 oh, I am sorry. The gentlelady from Illinois, Ms. Schakowsky,
5490 is recognized for 5 minutes to discuss the amendment.

5491 Ms. Schakowsky. Thank you, Mr. Chairman. The development
5492 of antimicrobial agents is one of the most successful medical
5493 developments. Before them, a paper cut could kill you. But as
5494 we have seen an increased use and misuse especially of
5495 antibiotics, the bacteria have evolved to be resistant, many of
5496 them anyway. This means more and more bacteria cannot be killed
5497 with traditional antibiotics, making antibiotics less effective.

5498 As my friend and a champion on this issue for many decades,
5499 Representative Louise Slaughter, stated, and this is really why
5500 I wanted to bring it up because this was Louise, one of her major
5501 issues. This is what she said, quote, antibiotic resistance
5502 threatens modern medicine. The scale and potential harm to
5503 public health from this crisis are almost unimaginable, unquote.
5504 More than 80 percent of the antibiotics used in the country are
5505 used on healthy farm animals. The National Academy of Sciences

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5506 estimated that livestock consumed over 63 tons of antibiotics in
5507 2010 and expect the number to increase by 67 percent by 2030.

5508 So we need to safeguard the antibiotics that we have and
5509 overuse in food production can't be acceptable. We can't trade
5510 our ability to fight deadly infectious diseases so a livestock
5511 producer can cut corners and overuse antibiotics. As
5512 Representative Slaughter pointed out, quote, feeding farm animals
5513 antibiotics for disease prevention is like sprinkling them on your
5514 children's Cheerios in the morning to keep them from getting sick.
5515 It is just unconscionable, unquote. That is what Louise said.

5516 As we have been considering the Animal Drug User Fee
5517 reauthorization, I hope we could include provisions that would
5518 safeguard the use of these valuable antibiotics. And I am hoping
5519 that as we move forward we could do this and that is really it.
5520 I wanted to say that as we move toward passage out of committee
5521 that we would consider adding something to this legislation.

5522 And I yield back unless anybody else wants my time.

5523 Mr. Burgess. The gentlelady yields back. Is there any
5524 other member wishing to be heard on the amendment?

5525 If not, the question is on the Schrader amendment to H.R.
5526 5554. Do you request a recorded vote?

5527 All those in favor will signify by saying aye.

5528 Those opposed, no.

5529 The ayes appear to have it. The ayes have it and the

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5530 amendment is adopted. Is there further discussion?

5531 For what purpose does the gentleman from North Carolina seek
5532 recognition?

5533 Mr. Hudson. Mr. Chairman, I would like to strike the last
5534 word.

5535 Mr. Burgess. The gentleman is recognized for 5 minutes.

5536 Mr. Hudson. Thank you, Mr. Chairman. I would like to speak
5537 in favor of this bill. And I first want to thank my colleagues,
5538 Representative Markwayne Mullin, the always eloquent member, and
5539 Representative Kurt Schrader, who I would have to say your input
5540 is very valid, in my opinion, for your leadership on this bill.
5541 The reauthorization of the user fees is critical to the timely
5542 approval of animal drugs and I applaud your work to put this great
5543 bill together.

5544 Further, I would like to speak about the Animal Health and
5545 Innovation Act, a bill I introduced yesterday with Representative
5546 Schrader, Bucshon, Butterfield, and Mullin, to expand conditional
5547 approval to include major uses, major species. Right now there
5548 are numerous unmet medical needs in veterinary medicine due to
5549 the complexity of providing clinical efficacy. Two examples
5550 paint the picture as to why this bill is necessary, degenerative
5551 joint disease in dogs, cats, and horses, and blackhead disease
5552 in turkeys.

5553 Degenerative joint disease is a crippling condition that

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5554 develops slowly over time. Right now there are no treatments to
5555 slow this progression, only treatments to mask the pain and
5556 inflammation. Expanding conditional approval will allow full
5557 collection of clinical efficacy data over time creating
5558 opportunities for drug development.

5559 Blackhead disease is a random biological event that can wipe
5560 out an entire turkey flock within weeks, resulting in a
5561 devastating setback to any farmer in North Carolina it strikes.
5562 Because blackhead disease is a random biological event, it is
5563 challenging to design a full-scale clinical trial to gather the
5564 necessary data to prove efficacy. Expanding conditional
5565 approval will allow a drug that is proven safe to collect efficacy
5566 data when blackhead disease pops up, helping farmers save their
5567 flocks. We need to give drug developers the tools they need to
5568 develop these drugs to pet owners, farmers, and veterinarians who
5569 need them to save their animals.

5570 Lastly, I would like to submit these letters of support for
5571 the record that come from 29 organizations who are asking for an
5572 expanded conditional approval to be included in this ADUFA
5573 reauthorization. I hope we can work together, Mr. Chairman, and
5574 include this additional tool in the underlying legislation.

5575 Mr. Burgess. Without objection, so ordered, for those
5576 letters for the record.

5577 [The information follows:]

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5578

5579

***** COMMITTEE INSERT 52 *****

5580 Mr. Hudson. Thank you, Mr. Chairman. I yield back.

5581 Mr. Burgess. The gentleman yields back. Are there other
5582 members that wish to be heard on H.R. 5554?

5583 Seeing none, the question now occurs on forwarding H.R. 5554
5584 to the full committee, as amended, to the full committee.

5585 All those in favor will say aye.

5586 Those opposed, no.

5587 The ayes appear to have it. The ayes have it and the bill
5588 is agreed to.

5589 It is now in order that the chair calls up the Committee Print
5590 entitled, 21st Century Tools for Pain and Addiction Treatment,
5591 Number 60 on the list, and asks the Clerk to report.

5592 [The information follows:]

5593

5594 ***** COMMITTEE INSERT 53 *****

5595 The Clerk. Discussion draft to require the Secretary of
5596 Health and Human Services to issue guidance with respect to the
5597 expedited approval of certain drugs, and for other purposes.

5598 Mr. Burgess. Without objection, the first reading of the
5599 bill is dispensed with. The bill is open for amendment at any
5600 point, so ordered. Are there any bipartisan amendments to the
5601 bill?

5602 Are there any amendments to the bill?

5603 Seeing none, the chair will recognize himself for 5 minutes
5604 to speak on the bill. This is a discussion draft that would direct
5605 the Food and Drug Administration to hold public meetings and issue
5606 or update guidance documents for the purposes of clarifying
5607 expedited regulatory pathways for non-addictive products to treat
5608 pain and addiction.

5609 The development of innovative therapies for treating pain
5610 and addiction is a significant factor in taking on the current
5611 opioid crisis and thwarting future addiction. During this
5612 subcommittee's legislative hearing on public health policies to
5613 address the crisis, we heard from the biopharmaceutical industry
5614 about the negligible level of investment in developing novel
5615 treatments for pain and addiction. According to data cited by
5616 one of our witnesses, less than four percent of the total venture
5617 investment in the pharmaceutical sector is being directed into
5618 companies whose lead product is novel pain therapy.

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5619 Additionally, over the last decade, companies working on novel
5620 pain therapies have received 17 times less funding than companies
5621 working on oncology drugs with even less investment for the
5622 development of novel therapies for addiction.

5623 To ensure that the medical product manufacturers developing
5624 novel pain addiction treatments can efficiently navigate the Food
5625 and Drug Administration, this bill would clarify the FDA's
5626 criteria for qualifying for expedited pathways like breakthrough
5627 designation and accelerated approval. The draft is not intended
5628 to create any confusion with the respect to the way products for
5629 other disease states qualify for expedited pathways nor is it
5630 intended to expand or modify those pathways. I will continue to
5631 work with the Food and Drug Administration to ensure that we avoid
5632 any such unintended consequences.

5633 I am committed to working with colleagues on both sides of
5634 the dais, with stakeholders, experts in the field to make certain
5635 that we get the policy right because I believe it is an important
5636 one in the battle against opioids. I urge the members of the
5637 subcommittee to support the passage of this draft and forwarding
5638 it on to the full committee. I am going to yield back and I will
5639 recognize the ranking member of the full committee, the gentleman
5640 from New Jersey, for 5 minutes.

5641 Mr. Pallone. Thank you, Mr. Chairman.

5642 And I strike the last word in opposition to the bill. Like

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5643 my colleagues on the other side of the aisle, I share the goal
5644 of encouraging the development of alternative treatments and want
5645 to work with FDA and the industry to do so. And that is why I
5646 am supportive of the agency hosting public meetings with industry
5647 and other stakeholders to discuss any issues, concerns, or
5648 barriers there may be to the development of these products today
5649 and how these may be overcome.

5650 Unfortunately, industry has said that this is not enough and
5651 that manufacturers need an incentive to invest in developing these
5652 products such as eligibility for accelerated approval which
5653 shortens the time for review, or breakthrough therapy designation
5654 and which would grant sponsors intensive assistance from the
5655 agency. And this could be achieved through new final guidance
5656 or updated guidance expanding upon how FDA will apply these
5657 pathways for novel pain and addiction treatment.

5658 I agree that if a product is eligible for these pathways under
5659 current law then those pathways should be available. However,
5660 we must be cautious that any new legislation not undermine the
5661 success of these pathways. I worry that FDA is required to issue
5662 such guidance it could unintentionally raise questions about
5663 whether the criteria applies differently for each therapeutic
5664 area, opening the agency up to a flood of requests for therapeutic
5665 areas' specific guidances about the eligibility for these
5666 pathways.

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5667 I am also concerned, Mr. Chairman, that if such guidance
5668 expands the eligibility requirements for the pain and addiction
5669 product area that we may unintentionally weaken the benefits of
5670 accelerated approval and breakthrough therapy designation
5671 pathways by expanding it to even more products. I just would
5672 remind my colleagues that if we continue to make more and more
5673 products eligible for the accelerated approval and the
5674 breakthrough therapy pathways, we may end up in a situation where
5675 everything is accelerated or breakthrough.

5676 And we should be mindful of the resource burden that these
5677 pathways put on the agency. The accelerated timeline and
5678 increased communication and assistance with the agency have a
5679 direct impact on the agency's resources and staff capacity. For
5680 example, in response to the overwhelming popularity of the
5681 breakthrough therapy designation process, additional resources
5682 were provided to address the demand in the recent reauthorization
5683 of PDUFA. But this does not take into account though any
5684 additional resources that may be needed to meet the demands of
5685 this legislation.

5686 And, finally, I want to raise concerns regarding the
5687 reporting of metrics included in this legislation. While I
5688 normally share the goal of increased transparency related to how
5689 the agency is meeting certain metrics or goals, the reporting
5690 requirements under this legislation are burdensome and would

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5691 result in the staff working on annual reports taking time away
5692 from the development and review of pain and addiction, and the
5693 data points required could unintentionally reveal confidential
5694 information regarding what companies are developing in this area.

5695 So it is for all these reasons that I can't support the bill.
5696 I appreciate the efforts of the majority to address the concerns
5697 we have raised and we can continue to work to address the
5698 unintentional consequences that I am concerned about and to
5699 minimize the burden on the agency moving forward. But right now
5700 I just think that this process is really going to, you know, be
5701 too burdensome. You know, open the door to all kinds of other
5702 problems and other demands and make it literally impossible for
5703 FDA to meet those demands.

5704 So on this one I do feel very strongly that this is not ripe
5705 and shouldn't move to full committee. So I would urge my
5706 colleagues to vote no.

5707 Mr. Burgess. Will the gentleman yield?

5708 Mr. Pallone. Of course.

5709 Mr. Burgess. I just want to thank the gentleman for his very
5710 generous offer to continue to work with us. Even though he is
5711 opposed tonight, I hope to be able to convince him that this is
5712 indeed a valid policy going forward.

5713 The gentleman does yield back. Are there other members that
5714 wish to be heard on the bill?

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5715 Seeing none, the question then occurs on favorably reporting
5716 --
5717 Mr. Pallone. And I would ask for a roll call on this one.
5718 Mr. Burgess. -- the Committee Print. A recorded vote has
5719 been requested. The Clerk will call the roll.
5720 The Clerk. Mr. Guthrie?
5721 Mr. Guthrie. Aye.
5722 The Clerk. Mr. Guthrie votes aye.
5723 Mr. Barton?
5724 Mr. Barton. Aye.
5725 The Clerk. Mr. Barton votes aye.
5726 Mr. Upton?
5727 Mr. Upton. Aye.
5728 The Clerk. Mr. Upton votes aye.
5729 Mr. Shimkus?
5730 Mr. Shimkus. Aye.
5731 The Clerk. Mr. Shimkus votes aye.
5732 Mrs. Blackburn?
5733 Mrs. Blackburn. Aye.
5734 The Clerk. Mrs. Blackburn votes aye.
5735 Mr. Latta?
5736 Mr. Latta. Aye.
5737 The Clerk. Mr. Latta votes aye.
5738 Mrs. McMorris Rodgers?

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5739 Mrs. McMorris Rodgers. Aye.

5740 The Clerk. Mrs. McMorris Rodgers votes aye.

5741 Mr. Lance?

5742 Mr. Lance. Aye.

5743 The Clerk. Mr. Lance votes aye.

5744 Mr. Griffith?

5745 Mr. Griffith. Aye.

5746 The Clerk. Mr. Griffith votes aye.

5747 Mr. Bilirakis?

5748 Mr. Bilirakis. Aye.

5749 The Clerk. Mr. Bilirakis votes aye.

5750 Mr. Long?

5751 Mr. Long. Aye.

5752 The Clerk. Mr. Long votes aye.

5753 Mr. Bucshon?

5754 Mr. Bucshon. Aye.

5755 The Clerk. Mr. Bucshon votes aye.

5756 Mrs. Brooks?

5757 Mrs. Brooks. Aye.

5758 The Clerk. Mrs. Brooks votes aye.

5759 Mr. Mullin?

5760 Mr. Hudson?

5761 Mr. Hudson. Aye.

5762 The Clerk. Mr. Hudson votes aye.

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5763 Mr. Collins?
5764 Mr. Collins. Aye.
5765 The Clerk. Mr. Collins votes aye.
5766 Mr. Carter?
5767 Mr. Carter. Aye.
5768 The Clerk. Mr. Carter votes aye.
5769 Chairman Walden?
5770 The Chairman. Aye.
5771 The Clerk. Chairman Walden votes aye.
5772 Mr. Green?
5773 Mr. Engel?
5774 Ms. Schakowsky?
5775 Ms. Schakowsky. No.
5776 The Clerk. Ms. Schakowsky votes no.
5777 Mr. Butterfield?
5778 Mr. Butterfield. No.
5779 The Clerk. Mr. Butterfield votes no.
5780 Ms. Matsui?
5781 Ms. Matsui. No.
5782 The Clerk. Ms. Matsui votes no.
5783 Ms. Castor?
5784 Ms. Castor. No.
5785 The Clerk. Ms. Castor votes no.
5786 Mr. Sarbanes?

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5787 Mr. Sarbanes. No.

5788 The Clerk. Mr. Sarbanes votes no.

5789 Mr. Lujan?

5790 Mr. Lujan. No.

5791 The Clerk. Mr. Lujan votes no.

5792 Mr. Schrader?

5793 Mr. Schrader. No.

5794 The Clerk. Mr. Schrader votes no.

5795 Mr. Kennedy?

5796 Mr. Kennedy. No.

5797 The Clerk. Mr. Kennedy votes no.

5798 Mr. Cardenas?

5799 Ms. Eshoo?

5800 Ms. DeGette?

5801 Ms. DeGette. No.

5802 The Clerk. Ms. DeGette votes no.

5803 Mr. Pallone?

5804 Mr. Pallone. No.

5805 The Clerk. Mr. Pallone votes no.

5806 Chairman Burgess?

5807 Mr. Burgess. Aye.

5808 The Clerk. Chairman Burgess votes aye.

5809 Mr. Mullin?

5810 Mr. Mullin. Aye.

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5811 The Clerk. Mr. Mullin votes aye.

5812 Mr. Burgess. Are there other members wishing to be
5813 recorded?

5814 Seeing none, the Clerk will report the total.

5815 The Clerk. Mr. Chairman, on that vote there were 19 ayes
5816 and 10 noes.

5817 Mr. Burgess. 19 ayes and 10 noes, the Committee Print is
5818 forwarded, agreed to and forwarded to the full committee.

5819 The chair calls up Committee Print entitled, FDA and
5820 International Mail, Number 59, and asks the Clerk to report.

5821 [The information follows:]

5822

5823 ***** COMMITTEE INSERT 54 *****

5824 The Clerk. Discussion draft to amend the Federal Food,
5825 Drug, and Cosmetic Act with respect to the importation of certain
5826 drugs, and other purposes.

5827 Mr. Burgess. Without objection, the first reading of the
5828 bill is dispensed with and the bill is open for amendment at any
5829 point, so ordered. Are there bipartisan amendments to the bill?

5830 Are there other amendments to the bill?

5831 Mrs. Blackburn. Mr. Chairman, I have an amendment.

5832 [The amendment of Mrs. Blackburn follows:]

5833

5834 ***** COMMITTEE INSERT 55 *****

5835 Mr. Burgess. For what purpose does the gentlelady seek
5836 recognition?

5837 Mrs. Blackburn. Thank you, Mr. Chairman. I have an
5838 amendment that is at the desk and it is a --

5839 Mr. Burgess. The Clerk will report the amendment.

5840 The Clerk. Amendment to the discussion draft, offered by
5841 Mrs. Blackburn.

5842 Mr. Burgess. The gentlelady is recognized for 5 minutes on
5843 her amendment.

5844 Mrs. Blackburn. Thank you, Mr. Chairman. This one is a
5845 very simple amendment. It strikes a section from the bill, page
5846 5 line 14 through page 6 line 18, and this will be reflected in
5847 a bill that Mr. Pallone will bring up next, and so this amendment
5848 will avoid any duplicative language. And I yield back my time
5849 as I encourage passage of the amendment.

5850 Mr. Burgess. The chair appreciates the gentlelady's
5851 amendment. She yields back. Are there other members wishing to
5852 be heard on the Blackburn amendment?

5853 Seeing none, the question then occurs on adopting the
5854 Blackburn amendment.

5855 All those in favor will say aye.

5856 Those opposed, no.

5857 The ayes appear to have it. The ayes have it. The Blackburn
5858 amendment to the Committee Print is adopted. Is there further

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5859 discussion on the Committee Print, FDA and international mail?

5860 Mrs. Blackburn. Mr. Chairman?

5861 Mr. Burgess. For what purpose does the gentlelady seek
5862 recognition?

5863 Mrs. Blackburn. I seek recognition to strike the last word
5864 and speak on the bill.

5865 Mr. Burgess. The gentlelady is recognized for 5 minutes.

5866 Mrs. Blackburn. Thank you, Mr. Chairman.

5867 This bill deals with how the FDA processes suspicious
5868 packages of illicit drugs that enter through the International
5869 Mail Facilities. These drugs pose really serious problems across
5870 the country and Commissioner Gottlieb mentioned his concerns
5871 about this issue when he spoke to us last October.

5872 I specifically asked him what current laws on the book needed
5873 to be changed in order to facilitate their work in fighting this
5874 opioid crisis and he identified this issue and how they need
5875 operating efficiencies in these IMFs in addressing this crisis.
5876 And since that hearing I have worked with him and his staff on
5877 legislation that would streamline and enhance the FDA's tools to
5878 intercept illegal drugs when they come into the country through
5879 the mail.

5880 The FDA currently must establish that a pill or substance
5881 is intended to be used as a drug based on its labeling, but more
5882 and more packages are coming through the IMFs that are minimally

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5883 labeled or unlabeled. If they can't establish that something is
5884 a drug based on its labeling, the FDA's only option is to return
5885 it to the sender rather than taking action to prevent the drug
5886 from entering the U.S. by other means.

5887 This bill allows the FDA to establish that a substance or
5888 a pill is a drug if it contains an active pharmaceutical ingredient
5889 in a currently approved drug or in a drug in the approval pipeline.
5890 This change will save significant time for the FDA inspectors by
5891 expediting the first step in the process which is in determining
5892 whether or not a substance is a drug before they are able to
5893 determine whether the substance violates federal law that should
5894 prevent it from being permitted into the country.

5895 I appreciate the stakeholders who have reached out to share
5896 their concerns that the current language may be too broad and grant
5897 authorities to the agency that they did not need. Commissioner
5898 Gottlieb has identified this change as his number one priority,
5899 and we are committed to working with the agency and the
5900 stakeholders to ensure that the language is right. The bill also
5901 defines articles of concern so that the agency will be able to
5902 stop the import of substances that are imminent threats to public
5903 health, and expands the FDA's authorities to debar individuals
5904 and companies who consistently violate the law from continuing
5905 to import drugs.

5906 With that I yield back the balance of my time.

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5907 Mr. Burgess. Will the gentlelady yield?

5908 Mrs. Blackburn. The gentlelady yields.

5909 Mr. Burgess. This may well be one of the most important
5910 things we will do with this group of bills. I did go with Dr.
5911 Gottlieb to the International Mail Facility a few weeks ago and
5912 the stuff that is coming over the transom into this country through
5913 the international mails is truly, it is just astounding.

5914 And the reason this is so critically important is the people
5915 who work there, the FDA inspectors who work there told us that
5916 there will be products that they recognize are problematic, but
5917 they don't have the authority to destroy them. They are required
5918 to send them back and that they will be recycled and they will
5919 see packages come back in that they have already marked up and
5920 they may come in another time or two seeing if they can't test
5921 the system and come in.

5922 There are a lot of things we can do as far as addressing the
5923 opioid crisis, but if we don't fix this problem it is going to
5924 be very, very difficult to get on top of it. So I thank you for
5925 bringing it. I thank you for working with members on the other
5926 side of the dais. I think this is just critically important. I
5927 will yield back to the gentlelady who will yield back.

5928 Mrs. Blackburn. And I yield back.

5929 Mr. Burgess. Thank you.

5930 Are there other members wishing to be heard on this

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5931 legislation?

5932 Seeing none, the question now occurs on forwarding the
5933 Committee Print, as amended, to the full committee.

5934 All those in favor will signify by saying aye.

5935 Those opposed, no.

5936 The ayes appear to have it. The ayes have it, and the bill
5937 is agreed to.

5938 The chair calls up H.R. 5228.

5939 [The bill follows:]

5940

5941 ***** COMMITTEE INSERT 56 *****

5942 Mr. Burgess. Number 57 on the list, and asks the Clerk to
5943 report.

5944 The Clerk. H.R. 5228, to strengthen the authorities of the
5945 Food and Drug Administration to address counterfeit drugs,
5946 illegal and synthetic opioids and opioid-like substances, and for
5947 other purposes.

5948 Mr. Burgess. Without objection, the first reading of the
5949 bill is dispensed with and the bill is open for amendment at any
5950 point, so ordered. Are there bipartisan amendments to the bill?

5951 Are there amendments to the bill?

5952 For what purpose does the gentleman from New Jersey seek
5953 recognition?

5954 Mr. Pallone. Mr. Chairman, I have an amendment at the desk.

5955 [The amendment of Mr. Pallone follows:]

5956

5957 ***** COMMITTEE INSERT 57 *****

5958 Mr. Pallone. I guess it is 01.

5959 Mr. Burgess. The Clerk will report the amendment.

5960 The Clerk. Amendment to H.R. 5228, offered by Mr. Pallone.

5961 Mr. Burgess. The gentleman is recognized for 5 minutes on
5962 his amendment.

5963 Mr. Pallone. Thank you, Mr. Chairman.

5964 As we have heard, there has been bipartisan and bicameral
5965 interest in working with FDA to address the illicit drug
5966 importation that is happening at our International Mail
5967 Facilities, and strengthening FDA's enforcement tools to help
5968 deter dangerous and unlawful behavior from bad actors. My
5969 amendment reflects the bipartisan work on this issue and works
5970 to harmonize the SCREEN Act with the FDA International Mail
5971 Facility discussion draft offered by Representative Blackburn.
5972 It also makes technical changes to address concerns raised by
5973 stakeholders to align the emergency recall authority for drugs
5974 to that of biologics and clarifies FDA's administrative
5975 destruction authority related to international mail.

5976 And I hope that moving forward we can continue working with
5977 FDA and stakeholders to address outstanding concerns and ensure
5978 that we are able to finally equip FDA with the resources they need
5979 to address and deter illicit opiate and fentanyl importation
5980 happening through our International Mail Facilities. So I urge
5981 my colleagues to support the amendment. I yield back, Mr.

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5982 Chairman.

5983 Mr. Burgess. The gentleman yields back.

5984 Does anyone else wish to be heard on the Pallone amendment
5985 to H.R. 5228?

5986 Seeing no additional requests for time, the question is then
5987 on approval of the Pallone amendment.

5988 All those in favor will signify by saying aye.

5989 Those opposed, no.

5990 The ayes appear to have it. The ayes have it and the
5991 amendment is agreed to.

5992 Is there any other member that wish to be heard on the
5993 underlying bill, 5228?

5994 Seeing none, the question then occurs on forwarding H.R.
5995 5228, as amended, to the full committee.

5996 All those in favor will signify by saying aye.

5997 Those opposed, no.

5998 The ayes appear to have it. The ayes have it, and the bill
5999 is agreed to.

6000 The chair calls up Committee Print entitled, FDA Opioid
6001 Sparing, Number 51 -- I am sorry, Number 61 on the list, and asks
6002 the Clerk to report.

6003 [The information follows:]

6004

6005 ***** COMMITTEE INSERT 58 *****

6006 The Clerk. Discussion draft to direct the Secretary of
6007 Health and Human Services to update or issue one or more guidances
6008 addressing alternative methods for data collection on opioid
6009 sparing and inclusion of such data and product labeling, and for
6010 other purposes.

6011 Mr. Burgess. Without objection, the first reading of the
6012 bill is dispensed with. The bill is open for amendment at any
6013 point, so ordered. Are there any bipartisan amendments to the
6014 bill?

6015 Are there any amendments to the bill?

6016 Does any member wish to be heard on the bill?

6017 Mr. Lujan from New Mexico, for what purpose do you seek
6018 recognition?

6019 Mr. Lujan. Strike the last word, Mr. Chairman.

6020 Mr. Burgess. The gentleman is recognized for 5 minutes.

6021 Mr. Lujan. Thank you, Mr. Chairman.

6022 I think I have said this at least a hundred times at this
6023 point, but we must work with our pharmaceutical partners and the
6024 FDA to make sure that patients across the country have access to
6025 non-addictive pain management options. I come from a blue collar
6026 district with ironworkers and ranchers and a whole lot of jobs
6027 where wear and tear on the body is inevitable. It is simply
6028 unrealistic to think we won't have people who need access to this
6029 medication. But that is where non-addictive therapies come in.

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6030 This bill is another step forward in making sure that everyone
6031 has more options to treat pain. I thank the chairman and I yield
6032 back.

6033 Mr. Burgess. Would the gentleman yield?

6034 Mr. Lujan. I certainly would yield to the chairman.

6035 Mr. Burgess. And it is my understanding that this is work
6036 you have done with Representative Comstock of Virginia. So it
6037 is acknowledged that it will take steps to facilitate the
6038 development of products that reduce, replace, or prevent the use
6039 of opioids. Specifically, this legislation will direct the FDA
6040 to hold a public meeting and update the agency's guidance on opioid
6041 sparing data that can be used to support updated product labeling
6042 and claims. By reducing the need to start an opioid in the first
6043 place you can stop addiction before it starts, save lives in the
6044 process. I urge my colleagues to vote in favor of this
6045 common-sense, noncontroversial measure.

6046 I yield back to the gentleman from New Mexico.

6047 Mr. Lujan. I yield back, Mr. Chairman. Thank you.

6048 Mr. Burgess. The gentleman yields back. Does any other
6049 member wish to be heard on the FDA Opioid Sparing Committee Print?

6050 Seeing no other members seeking time, the question now occurs
6051 on forwarding the Committee Print to the full committee.

6052 All those in favor will signify by saying aye.

6053 Those opposed, no.

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6054 The ayes appear to have it. The ayes have it, and the bill
6055 is agreed to.

6056 Mr. Burgess. The chair calls up a Committee Print entitled
6057 FDA Misuse Abuse, Number 64, and asks the Clerk to report.

6058 [The information follows:]

6059

6060 ***** COMMITTEE INSERT 59 *****

6061 Mr. Burgess. Number 64.

6062 The Clerk. Discussion draft to amend the Federal Food,
6063 Drug, and Cosmetic Act to authorize the Secretary of Health and
6064 Human Services to consider the potential for misuse and abuse when
6065 determining whether to approve certain drugs, and for other
6066 purposes.

6067 Mr. Burgess. Without objection, the first reading of the
6068 bill is dispensed with and the bill is open for amendment at any
6069 point, so ordered. Are there bipartisan amendments to the bill?

6070 Are there other amendments?

6071 Mr. Green. Mr. Chairman, I would like to strike the last
6072 word.

6073 Mr. Burgess. The gentleman is recognized for 5 minutes to
6074 speak on the bill.

6075 Mr. Green. Mr. Chairman, I would like to speak in support
6076 of the misuse and abuse discussion draft. During our March
6077 legislative hearing, FDA commissioner, or Director Scott Gottlieb
6078 testified that the issue of opioid misuse and abuse is one of the
6079 agency's highest priorities. Last year, the FDA acted when it
6080 requested to withdraw an opioid treatment due to the concern that
6081 the benefits associated with the product were outweighed by the
6082 risk of the abuse and manipulation.

6083 Clarifying the FDA's authority to take potential risk for
6084 abuse and misuse into consideration is an important step to combat

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6085 the opioid crisis. Currently, we are working with the FDA and
6086 stakeholders on making sure the language is in the right place
6087 and I ask for the subcommittee's support while we continue to work
6088 on this important legislation and a key step in the federal
6089 government's effort against opioid abuse and misuse. And I yield
6090 back my time.

6091 Mr. Burgess. Would the gentleman yield to the gentleman
6092 from Georgia?

6093 Mr. Green. Glad to.

6094 Mr. Burgess. The gentleman from Georgia?

6095 Mr. Carter. Mr. Chairman, I move to strike the last word.
6096 I understand that the FDA may currently require risk evaluation
6097 and mitigation strategy, REMS, to ensure that a medicine's
6098 benefits outweigh its risk. FDA may tailor the REMS to specific
6099 risks associated with the medicine. By mitigating those risks,
6100 the REMS can allow patients safe access to medicines that
6101 otherwise could not be approved.

6102 Indeed, the FDA has used its REMS authority to address the
6103 potential for abuse and misuse of certain opioid products. This
6104 bill could grant FDA overly broad disapproval and withdraw
6105 authorities and could lead to questions about why these new
6106 statutory authorities are necessary in light of FDA's existing
6107 REMS authority for controlled substances. I understand the
6108 sponsors are committed to working through these problems and I

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6109 stand ready to help.

6110 I want to thank those involved, including Ranking Member
6111 Green, for their diligent work on this issue and I yield back.

6112 Mr. Burgess. The chair thanks the gentleman. The
6113 gentleman yields back. Is there any other member that wishes to
6114 be heard on FDA Misuse Number 64?

6115 Seeing none, the question now occurs on forwarding the
6116 Committee Print to the full committee.

6117 All those in favor signify by saying aye.

6118 All those opposed, no.

6119 The ayes appear to have it. The ayes have it, and the bill
6120 is agreed to.

6121 Mr. Burgess. The chair calls up Committee Print entitled,
6122 FDA Packaging and Disposal, Number 62, and asks the Clerk to
6123 report.

6124 [The information follows:]

6125

6126 ***** COMMITTEE INSERT 60 *****

6127 The Clerk. Discussion draft to amend the Federal Food,
6128 Drug, and Cosmetic Act to require improved packaging and disposal
6129 methods with respect to certain drugs, and for other purposes.

6130 Mr. Burgess. Without objection, the first reading of the
6131 bill is dispensed with. The bill is open for amendment at any
6132 point, so ordered. Are there bipartisan amendments to the bill?

6133 Are there any other amendments to the bill?

6134 Does any member wish to be heard on the bill?

6135 For what purpose does the gentleman from North Carolina seek
6136 recognition?

6137 Mr. Hudson. Mr. Chairman, I would like to speak in favor
6138 of the bill.

6139 Mr. Burgess. The gentleman is recognized for 5 minutes.

6140 Mr. Hudson. Thank you, Mr. Chairman.

6141 In North Carolina we have four of the top 25 worst cities
6142 for abuse in the country, one of which is in my district,
6143 Fayetteville, North Carolina. This issue is personal to me and
6144 my constituents, and I know that it is personal for everyone on
6145 this committee.

6146 This bill will direct the FDA to work with manufacturers to
6147 establish programs for efficient return or destruction of unused
6148 Schedule II or Schedule III opioids. These methods could include
6149 mail-back pouches to secure facilities for incineration, or
6150 methods to immediately inactivate or render unattractive unused

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6151 drugs. In addition, this bill will facilitate utilization of
6152 packaging that will help reduce diversion, overprescribing, or
6153 abuse of Schedule II or Schedule III opioids.

6154 Finally, this bill will require the Government Accounting
6155 Office to study new and innovative technologies that claim to be
6156 able to safely dispose of opioids and other unused medications.
6157 GAO would review and detail the effectiveness of these disposal
6158 methods. I have found that almost everyone I have a conversation
6159 with about leftover opioids has a light go off. They either have
6160 or have had an unused bottle of prescription opioids sitting in
6161 their medicine cabinet at home from past surgeries. One person
6162 I talked to had had a bottle for over 5 years that she said she
6163 had carried from apartment to apartment as she had moved.

6164 I believe addressing leftover opioids from the front end with
6165 packaging, and on the back end with disposal, will help eliminate
6166 the leftover drugs that find their way onto the streets, and curb
6167 this epidemic. I don't believe there is one silver bullet
6168 solution that will fix this epidemic, just as I don't believe there
6169 is one culprit to this epidemic. I do believe this bill will help
6170 make a difference and I encourage my colleagues to join me in
6171 supporting its passage.

6172 Finally, I would like to submit a letter for the record from
6173 DisposeRx, an innovative company in my district that is
6174 championing new disposal technologies.

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6175 Mr. Burgess. Without objection, so ordered.

6176 [The information follows:]

6177

6178 ***** COMMITTEE INSERT 61 *****

6179 Mr. Hudson. Thank you, Mr. Chairman. And with that I yield
6180 back.

6181 Mr. Burgess. The gentleman yields back. The chair thanks
6182 the gentleman.

6183 For what purpose does the gentleman from New Jersey seek
6184 recognition?

6185 Mr. Pallone. To strike the last word in opposition to the
6186 bill.

6187 Mr. Burgess. The gentleman is recognized for 5 minutes.

6188 Mr. Pallone. One of the goals that I know all of the members
6189 of this committee share is working to reduce the number of unused
6190 opioids that are in circulation so that fewer individuals become
6191 addicted to these drugs. To that end, FDA has been supportive
6192 of exploring what role, if any, packaging and disposal
6193 technologies could play in helping to reduce misuse and abuse.

6194 And the agency actually held a public workshop on this issue
6195 last winter and more recently directed the manufacturers of
6196 loperamide to make changes to use blister packs or other single
6197 dose packaging options to limit the number of doses that could
6198 be abused or misused. And these are good first steps to better
6199 understanding whether these technologies do have the desired
6200 effect of reducing the number of opioids in circulation and
6201 working to impede the ability of these products to be abused. Mr.
6202 Gottlieb has noted that the use of technology such as packaging

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6203 merits consideration through a science-based process that I hope
6204 will continue.

6205 The legislation before us today will provide FDA with the
6206 authority to issue orders directing manufacturers of certain
6207 controlled substances to implement or modify technologies,
6208 controls, or measures related to the packaging or disposal of such
6209 drugs. While I appreciate that the revised draft is limited to
6210 Schedule II and III controlled substances and allows FDA the
6211 flexibility to permit a range of options for packaging or
6212 disposal, I have concerns about how implementation could impact
6213 legitimate patient access to these products and what impact this
6214 could have on generic competition.

6215 It is no secret that requiring manufacturers to implement
6216 new packaging technologies will carry a cost. These would be new
6217 requirements in addition to the current manufacturing costs which
6218 could result in changes to manufacturing lines, contracting with
6219 new supply chain partners, and testing to ensure that these
6220 technologies not impact the safety or quality. And I fear that
6221 this cost could then be passed down through the supply chain to
6222 patients and may threaten legitimate patient access. I'm also
6223 worried that there is potential that requiring use of packaging
6224 technologies or disposal methods could become a barrier to generic
6225 entry either through potential gamesmanship from brand
6226 manufacturers or from the inability of generic manufacturers to

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6227 meet the requirements.

6228 So I hope we can continue to work to address these issues
6229 as well as to ensure that FDA is carefully examining whether the
6230 public health benefits of implementing certain packaging
6231 outweighs the costs or potential burdens to patients in the supply
6232 chain. Again I oppose the legislation, but I do appreciate the
6233 fact that the sponsor and the majority have been trying to improve
6234 upon this and hopefully we will do even more as we move to full
6235 committee, Mr. Chairman.

6236 Mr. Burgess. The chair thanks the gentleman. The
6237 gentleman yields --

6238 Mr. Pallone. And I am not asking for a roll call.

6239 Mr. Burgess. Okay. Any other member wish to be heard on
6240 -- the gentleman from New York.

6241 Mr. Collins. Mr. Chair, I would yield my time to Mr. Hudson.

6242 Mr. Burgess. The gentleman is recognized for 5 minutes.

6243 Mr. Hudson. Thank you, Mr. Chairman.

6244 Thank you, Mr. Pallone, for your very thoughtful comments
6245 on this discussion. And this is a discussion draft. We are
6246 continuing to make improvements. We are getting input from
6247 stakeholders and we have made a number of changes that I think
6248 address a lot of the concerns you have raised. One is that you
6249 mentioned the cost increases and potential to pass along to other
6250 patients. I certainly appreciate this concern and share this

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6251 concern and I have made a concerted effort to ensure that the cost
6252 to patients will be considered because it is not my intention that
6253 this legislation create unnecessary burden on patients or
6254 providers.

6255 To be sure that FDA takes potential costs of packaging or
6256 disposal systems into consideration I have modified the original
6257 draft legislation on the input of various stakeholders.
6258 Specifically, the bill requires the secretary consult with a broad
6259 list of experts prior to issuing any orders related to packaging
6260 and disposal. Included on the list of experts are wholesalers,
6261 distributors, payers, basically to understand of how costs would
6262 be impacted. Based on input from the minority on the committee,
6263 we also are going to include patients on that list of stakeholders
6264 that must be consulted.

6265 The other concern Mr. Pallone raised was the risk that
6266 generic competitors could be blocked. Again this is a concern
6267 I share. It is not my intent to allow this to happen and this
6268 draft has been modified to ensure this is not the result. The
6269 new requirements will be established outside of the REMS system,
6270 the system frequently cited as being used by brand manufacturers
6271 to block generic competition. Therefore the restrictions of REMS
6272 will not apply to packaging and disposal requirements under my
6273 bill. Under this new authority, the secretary may provide for
6274 a range of options for implementing the new packaging and disposal

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6275 requirements so if a generic manufacturer cannot access to certain
6276 packaging or disposal technology there will be alternative
6277 options for compliance.

6278 So I think we are actually going to be in a better situation
6279 than the status quo. Furthermore, manufacturers will have the
6280 ability to propose the packaging or disposal technology that works
6281 best for their products with the goal of reducing the risk or
6282 misuse or abuse.

6283 Finally, I will just close by saying that I am open to any
6284 and all proposals that my colleagues have to incorporate
6285 additional safeguards against this risk, but I think I would just
6286 encourage all members of this committee to work with me and let's
6287 continue to move forward and improve the legislation. I believe
6288 the concerns that were raised are not valid, the legislation in
6289 its current form, but I pledge to continue to work with everyone
6290 as we move forward to make sure we get this right. So with that
6291 --

6292 Mr. Butterfield. Will the gentleman yield?

6293 Mr. Hudson. I would be happy to yield.

6294 Mr. Butterfield. Mr. Hudson, I want to thank you for working
6295 on this bill. My office has been working very closely with you
6296 on it. I think the goal of the bill is very laudable. I think
6297 we can get there. I have talked to Mr. Pallone privately about
6298 this and I have every confidence that we will be able to work

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6299 together and get a good piece of legislation. So thank you for
6300 your work.

6301 Mr. Hudson. I thank the gentleman very much. And unless
6302 anyone else has a question, I would be happy to yield back to the
6303 chairman.

6304 Mr. Burgess. Does the gentleman from New York yield back?

6305 Mr. Collins. I yield back.

6306 Mr. Hudson. I yield back to the gentleman from New York.

6307 Mr. Burgess. The gentleman yields back. Is there any other
6308 member that wishes to be heard on the FDA packaging and disposal
6309 committee draft?

6310 The question now occurs on forwarding the Committee Print
6311 to the full committee.

6312 All those in favor say aye.

6313 Those opposed, no.

6314 The ayes appear to have. The ayes have it, and the Committee
6315 Print is agreed to.

6316 The chair calls up H.R. 4284.

6317 [The bill follows:]

6318

6319 ***** COMMITTEE INSERT 62 *****

6320 Mr. Burgess. This is Number 9 on the list, and asks the Clerk
6321 to report.

6322 The Clerk. H.R. 4284, to establish a federal coordinator
6323 within the Department of Health and Human Services, and for other
6324 purposes.

6325 Mr. Burgess. Without objection, the first reading of the
6326 bill is dispensed with, and the bill is open for amendment at any
6327 --

6328 Mr. Latta. Mr. Chairman.

6329 Mr. Burgess. -- point, so ordered. Are there bipartisan
6330 amendments to the bill?

6331 Are there other amendments to the bill?

6332 Mr. Latta. Mr. Chairman.

6333 Mr. Burgess. For what purpose does the gentleman from Ohio
6334 seek recognition?

6335 Mr. Latta. Thank you very much. I have an amendment in the
6336 nature of a substitute at the desk.

6337 [The amendment of Mr. Latta follows:]

6338

6339 ***** COMMITTEE INSERT 63 *****

6340 Mr. Burgess. The Clerk will report the amendment.

6341 The Clerk. Amendment in the nature of a substitute to H.R.
6342 4284, offered by Mr. Latta.

6343 Mr. Burgess. The gentleman is recognized for 5 minutes on
6344 his amendment.

6345 Mr. Latta. Thank you, Mr. Chairman. The amendment in the
6346 nature of a substitute to H.R. 4284, the Indexing Narcotics,
6347 Fentanyl, and Opioids Act, makes changes to clarify the purpose
6348 of the dashboard created under the proposed language and adds an
6349 interagency substance use disorder coordinating committee. The
6350 amendment focuses on the establishment of the substance use
6351 disorder information dashboard and the type of information and
6352 data published on the dashboard. It also creates an interagency
6353 committee consisting of federal and nonfederal members to provide
6354 HHS with a variety of recommendations relating to the opioid
6355 crisis. These changes reflect the guidance we received from
6356 stakeholders and the administration.

6357 And, Mr. Chairman, I yield back.

6358 Mr. Burgess. The chair thanks the gentleman. The
6359 gentleman yields back. And is there any other member that wishes
6360 to be heard on the Latta amendment to H.R. 4284?

6361 Seeing none, the question then occurs on adopting the Latta
6362 amendment to H.R. 4284.

6363 All those in favor will signify by saying aye.

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6364 Those opposed, no.

6365 The ayes appear to have it. The ayes have it.

6366 Is there any member who wishes to be recognized to speak on
6367 4284?

6368 Seeing none, the question then occurs on forwarding the H.R.
6369 4284 to the full committee. Do you wish a roll call vote, Mr.
6370 Pallone?

6371 All those favor will signify by saying aye.

6372 Those opposed, no.

6373 The ayes appear to have it. The ayes have it, and H.R. 4284
6374 is forwarded to the full committee.

6375 The chair calls up H.R. 4684.

6376 [The bill follows:]

6377

6378 ***** COMMITTEE INSERT 64 *****

6379 Mr. Burgess. Number 10 on the list, and asks the Clerk to
6380 report.

6381 The Clerk. H.R. 4684, to direct the Secretary of Health and
6382 Human Services, acting through the Director of the Center for
6383 Substance Abuse Treatment of the Substance Abuse and Mental Health
6384 Services Administration, to publish and disseminate best
6385 practices for operating recovery housing, and for other purposes.

6386 Mr. Burgess. Without objection, the first reading of the
6387 bill is dispensed with. The bill is open for amendment at any
6388 point, so ordered. Are there any bipartisan amendments to the
6389 bill?

6390 Are there any amendments to the bill?

6391 For what purpose does the gentleman from New Jersey seek
6392 recognition?

6393 Mr. Pallone. I have an amendment in the nature of a
6394 substitute that makes technical changes.

6395 [The amendment of Mr. Pallone follows:]

6396

6397 ***** COMMITTEE INSERT 65 *****

6398 Mr. Burgess. The Clerk will report.

6399 The Clerk. Amendment in the nature of a substitute to H.R.
6400 4684, offered by Mr. Pallone.

6401 Mr. Burgess. And the gentleman is recognized for 5 minutes
6402 on his amendment.

6403 Mr. Pallone. Thank you, Mr. Chairman.

6404 This bill would require HHS to work with stakeholders,
6405 including individuals with substance use disorders and recovery
6406 housing groups, to develop best practices for operating recovery
6407 housing. And our bipartisan investigation into disreputable
6408 sober homes and associated patient brokers in treatment
6409 facilities has made clear that we must do more to ensure that
6410 individuals with opioid use disorder are not being taken advantage
6411 of by entities seeking to treat such individuals as commodities
6412 rather than people in need of treatment. In fact, in far too many
6413 instances, these homes and providers offered no treatment at all.
6414 In other instances, what treatment is offered is only provided
6415 to increase the provider's profits.

6416 In the worst instances, these rogue providers go so far as
6417 to help individuals stop their illicit use of opiates for the
6418 duration of their insurance limit for a given treatment service,
6419 only to supply opiates to these same individuals after they are
6420 released so they can relapse and their insurance once again can
6421 be milked for the duration of the benefit limit. And such

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6422 providers are not only harmful to patients trying to stop their
6423 illicit use of opioids and enter recovery this substandard
6424 treatment also costs many individuals their lives.

6425 Our investigation also has revealed that individuals with
6426 opioid use disorder and their families are particularly
6427 susceptible to such schemes because there is not adequate
6428 information available to help them determine whether a facility
6429 is a quality provider of recovery housing or to detect the
6430 fraudulent intent of such actors. Many rely on bad information
6431 obtained through internet searches or questionable referrals from
6432 individuals who are actually patient brokers and paid to deliver
6433 patients to the highest bidding sober home or treatment provider.

6434 So the bill aims to prevent this often tragic consequence
6435 of the patient brokering schemes that send individuals to low
6436 quality sober homes. The legislation requires HHS in
6437 coordination with the Department of Housing and Urban Development
6438 and with stakeholders to establish best practices that will aid
6439 states in establishing standards for the recovery houses, helping
6440 recovery housing providers in establishing and maintaining
6441 housing that meets the highest quality standards, and help
6442 individuals and their families to identify what to look for in
6443 a quality provider.

6444 So again the amendment is technical and I would ask members
6445 to support it and to support the underlying bill.

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6446 Mr. Burgess. And the gentleman yields back. Is there any
6447 other member that wishes to be heard on the technical amendment?

6448 The Chairman. Mr. Chairman? Mr. Chairman?

6449 Mr. Burgess. The gentleman from Oregon recognized for 5
6450 minutes.

6451 The Chairman. I would like to speak on not just the
6452 amendment but the underlying bill as well. At our impact hearing
6453 last week, the roundtable with the victims' families, this was
6454 an issue that came up for those who were there and it was just
6455 tragic to hear the story of a family who sent their -- they were
6456 able to afford to send their child into treatment down in actually
6457 in Florida, I think they said. They ended up in a patient
6458 brokering, it appeared, issue, one house to another to another,
6459 and because of some other federal restrictions that prevented the
6460 sharing of communication they were not made aware this was
6461 occurring.

6462 This is really, really important to get a patient brokering.
6463 This has been part of our investigation on the Oversight and
6464 Investigations Subcommittee. That investigation for the last
6465 year and a half or thereabouts is lending, data out of that is
6466 lending itself to this type of legislation going forward, and I
6467 just commend the sponsors of this bill and support the amendment
6468 and the bill. This is really critical to do, and I yield back.

6469 Mr. Burgess. Would the gentleman yield to me?

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6470 The Chairman. Before I yield back and I would like to yield
6471 to the gentleman from Texas, the chairman of the subcommittee.

6472 Mr. Burgess. And I thank the gentleman, and you are very
6473 correct. The panel that we heard from last Thursday a third of
6474 the losses that were discussed, I think we had nine witnesses and
6475 three of those losses were directly attributable to unlicensed
6476 and unrestricted group homes and sober homes. And it really was,
6477 it was heartbreaking that people that recognized they had a
6478 problem were going into treatment and then the treatment ended
6479 up being just as deleterious as the underlying substance use
6480 disorder. So it is critical that we get this right.

6481 And additionally, of course, I do want to acknowledge the
6482 good work done by the Oversight and Investigations Subcommittee.
6483 That is actually where this issue first came to light to our
6484 members of that subcommittee when we had a very detailed and
6485 involved hearing on this, and I just can't underscore enough how
6486 important it is that we get this aspect right. And I will yield
6487 back to the gentleman from Oregon. Will you yield to the
6488 gentleman from Florida?

6489 The Chairman. I would do that. I would yield to the
6490 gentleman, my friend from Florida, Mr. Bilirakis.

6491 Mr. Bilirakis. Thank you so much, Mr. Chairman. I
6492 appreciate it, and well put. These patients and the family
6493 members don't know where to turn to. And, you know, I believe

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6494 we need some kind of a ratings system, an accurate ratings system.
6495 And I do have some prepared remarks.

6496 Patient brokering is and continues to be an issue in Florida
6497 as it is, more than likely, in other parts of the country. An
6498 increased demand for substance use disorder treatment has sadly
6499 attracted bad actors to the treatment space in order to make a
6500 quick buck by taking advantage of patients. This is despicable
6501 and it has to stop.

6502 Currently, regulations for addiction treatment providers
6503 vary from state to state and are virtually nonexistent in some
6504 states. As a result, patients and families are unable to
6505 confidently identify quality providers of recovery treatment.
6506 They are going through so much in dealing with their loved one
6507 and then they can't find a good place. They can't rely on a good
6508 place once maybe the loved one leaves the treatment center and
6509 goes into one of these sober homes. Again I feel that it is a
6510 great concept. It is a tremendous concept, but we have got to
6511 weed out the bad guys.

6512 You know what, Mr. Chairman, I am going to go ahead and yield
6513 back the balance of my time in the interest of time. But I really
6514 appreciate Judy Chu from California, congresswoman from
6515 California, sponsoring this bill along with many co-sponsors.
6516 And we have got to get this through. We have got to do it for
6517 our kids. So thank you very much for giving me the time, Mr.

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6518 Chairman. I appreciate it.

6519 The Chairman. You are more than welcome. Thanks for your
6520 leadership on this and the other members who have been so active.
6521 This is a really, really important piece of legislation. And with
6522 that, Mr. Chairman, I yield back.

6523 Mr. Burgess. The gentleman yields back. The chair thanks
6524 the gentleman. Is there any other member that wishes to be heard
6525 on the technical amendment of Mr. Pallone to H.R. 4684?

6526 Seeing none, the question then occurs on adoption of the
6527 Pallone amendment.

6528 Those in favor will signify by saying aye.

6529 Those opposed, no.

6530 The ayes appear to have it. The ayes have it, and the
6531 amendment is adopted. Is there further discussion of the bill,
6532 as amended?

6533 Seeing none, the question now occurs on forwarding H.R. 4684,
6534 as amended, to the full committee.

6535 All those in favor will signify by saying aye.

6536 Those opposed, no.

6537 The ayes appear to have it, and the bill is agreed to.

6538 The chair calls up H.R. 5176.

6539 [The bill follows:]

6540 ***** COMMITTEE INSERT 66 *****

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6541 Mr. Burgess. Number 14 on the list, and asks the Clerk to
6542 report.

6543 The Clerk. H.R. 5176, to require the Secretary of Health
6544 and Human Services to provide coordinated care to patients who
6545 have experienced a non-fatal overdose after emergency room
6546 discharge, and for other purposes.

6547 Mr. Burgess. Without objection, the first reading of the
6548 bill is dispensed with, and the bill is open for amendment at any
6549 point, so ordered.

6550 The chair recognizes himself to offer an amendment in the
6551 nature of a substitute.

6552 [The amendment of Mr. Burgess follows:]

6553

6554 ***** COMMITTEE INSERT 67 *****

6555 Mr. Burgess. And the Clerk will report the amendment.

6556 The Clerk. Amendment in the nature of a substitute to H.R.
6557 5176, offered by Mr. Burgess.

6558 Mr. Burgess. The chair recognizes himself to offer the
6559 amendment in the nature of a substitute, on behalf of
6560 Representative McKinley, to H.R. 5176, Preventing Overdoses While
6561 in Emergency Rooms Act of 2018. The amendment makes technical
6562 and conforming changes to the bill and also grants, allows the
6563 grants to be used for consultation with and referral to support
6564 services that aid in substance abuse treatment and recovery. It
6565 also directs the secretary to report on the effectiveness of a
6566 practitioner on site to administer and initiate medication
6567 assisted treatment.

6568 Is there any other member that wishes to be heard on the
6569 amendment?

6570 Seeing none, the question then occurs on adoption of the
6571 amendment to the McKinley bill 5176.

6572 All those in favor will signify by saying aye.

6573 Those opposed, no.

6574 The ayes appear to have it. The ayes have it. Are there
6575 members that wish to be recognized on the underlying bill 5176?

6576 Seeing none, the question, if there is no further discussion,
6577 the question now occurs on forwarding H.R. 5176 to the full
6578 committee.

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6579 All those in favor will say aye.

6580 Those opposed, no.

6581 The ayes appear to have it. The ayes have it, and the bill
6582 is agreed to, as amended.

6583 The chair calls up H.R. 5197.

6584 [The bill follows:]

6585

6586 ***** COMMITTEE INSERT 68 *****

6587 Mr. Burgess. This is Number 15 on the list, and asks the
6588 Clerk to report.

6589 The Clerk. H.R. 5197, to direct the Secretary of Health and
6590 Human Services to conduct a demonstration program to test
6591 alternative pain management protocols to limit the use of opioids
6592 in emergency departments.

6593 Mr. Burgess. Without objection, the first reading of the
6594 bill is dispensed with. The bill is open for amendment at any
6595 point, so ordered. Are there any bipartisan amendments to the
6596 bill?

6597 Are there other amendments?

6598 Is there any member wishing to -- for what purpose does the
6599 gentleman from New Jersey seek recognition?

6600 Mr. Pallone. Mr. Chairman, I have an amendment in the nature
6601 of a substitute.

6602 [The amendment of Mr. Pallone follows:]

6603

6604 ***** COMMITTEE INSERT 69 *****

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6605 Mr. Burgess. The Clerk will report the amendment.

6606 The Clerk. Amendment in the nature of a substitute to H.R.
6607 5197, offered by Mr. Pallone.

6608 Mr. Burgess. And the gentleman from New Jersey is
6609 recognized for 5 minutes in support of his amendment.

6610 Mr. Pallone. Thank you. This amendment makes technical
6611 changes to the underlying bill and I would like to talk about the
6612 amendment and the bill itself. The legislation would create a
6613 demonstration program to support emergency departments in
6614 developing, implementing, enhancing, or studying alternative
6615 pain management protocols and treatments that limit the use of
6616 prescription of opioids in emergency departments.

6617 As we have heard, many times the overuse and overprescribing
6618 of opioid medication to treat patients' pain has largely
6619 contributed to the epidemic. Finding alternatives to treat both
6620 acute and chronic painful conditions is key to decreasing the
6621 number of opioid prescriptions and preventing more people from
6622 becoming addicted. Opioids are frequently used in emergency
6623 departments to control acute pain, and the patients treated in
6624 emergency departments may then receive a prescription to control
6625 their pain at home.

6626 At our legislative hearing in March, our witness, Dr.
6627 Rosenberg, discussed the benefits of using an innovative protocol
6628 employed at St. Joseph Regional Medical Center in New Jersey, in

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6629 Mr. Pascrell's district, which uses non-opioid therapies to treat
6630 patients' pain in the emergency department. In the first year
6631 of use, these prescriptions, or opioid prescriptions dropped by
6632 nearly 60 percent and others have seen similar results such as
6633 the Colorado Hospital Association. Ms. DeGette, I think, is one
6634 of the co-sponsors of the bill. And there they experienced a
6635 decline of opioid usage by over 30 percent in 6 months.

6636 Innovative studies and protocols to treat pain without
6637 relying on opioid medication are integral in decreasing the number
6638 of opioids available in our community and exposure to these
6639 potentially addictive substances, and I believe that supporting
6640 the development of additional protocols for alternatives like the
6641 demonstration supported by this bill will help reduce the number
6642 of those at risk from becoming addicted.

6643 So I encourage my colleagues to support the amendment as well
6644 as the underlying bipartisan bill.

6645 Mr. Burgess. The gentleman yields back. The chair thanks
6646 the gentleman. Is there any other member that wishes to be heard
6647 on the Pallone amendment to H.R. 5197?

6648 Seeing none, the question then occurs on favorably reporting
6649 the Pallone amendment.

6650 All those in favor will signify by saying aye.

6651 Those opposed, no.

6652 In the opinion of the chair the ayes have it. The amendment

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6653 is favorably reported. Is there any other member that seeks
6654 additional time on the bill?

6655 For what purpose does the gentlelady from Colorado seek
6656 recognition?

6657 Ms. DeGette. Move to strike the last word.

6658 Mr. Burgess. The gentlelady is recognized for 5 minutes.

6659 Ms. DeGette. I will be brief, Mr. Chairman, since Mr.

6660 Pallone just talked about the success in both Colorado and New

6661 Jersey of these programs. And I also want to thank Mr. McKinley

6662 for working on this amendment with us. It really makes a lot of

6663 sense to limit the use of opioids in the emergency rooms to where

6664 they are really, really needed and that just gets the patients

6665 off on the right foot. I would urge a yes vote and I yield back.

6666 Mr. Burgess. The chair thanks the gentlelady and the

6667 gentlelady yields back. Is there any other member that seeks time

6668 on H.R. 5197?

6669 Seeing none, the question now occurs on forwarding H.R. 5197,

6670 as amended, to the full committee.

6671 All those in favor will signify by saying aye.

6672 Those opposed, no.

6673 The ayes appear to have it. The ayes have it, and the bill

6674 is agreed to.

6675 The chair calls up H.R. 5272.

6676 [The bill follows:]

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6677

6678

***** COMMITTEE INSERT 70 *****

6679 Mr. Burgess. Number 17 on the list, and asks the Clerk to
6680 report.

6681 The Clerk. H.R. 5272, to ensure that programs and
6682 activities that are funded by a grant, cooperative agreement,
6683 loan, or a loan guarantee from the Department of Health and Human
6684 Services, and whose purpose to prevent or treat a mental health
6685 or substance use disorder, are evidence based.

6686 Mr. Burgess. Without objection, the first reading of the
6687 bill is dispensed with. The bill is open for amendment at any
6688 point, so ordered. And the chair will recognize himself to offer
6689 an amendment in the nature of a substitute.

6690 [The amendment of Mr. Burgess follows:]

6691

6692 ***** COMMITTEE INSERT 71 *****

6693 Mr. Burgess. And the Clerk will report the amendment.

6694 The Clerk. Amendment in the nature of a substitute to H.R.
6695 5272, offered by Mr. Burgess.

6696 Mr. Burgess. Without objection, the reading of the
6697 amendment is dispensed with, and I will recognize myself for 5
6698 minutes in support of the amendment.

6699 The chair recognizes himself to offer an amendment in the
6700 nature of a substitute, on behalf of Representative Steve Stivers
6701 of Ohio, to H.R. 5272, the Reinforcing Evidence-based Standards
6702 under Law in Treating Substance Abuse Act of 2018, also known as
6703 the RESULTS Act. This amendment strikes all language in the
6704 introduced version and enacts a section to bolster guidance from
6705 the Substance Abuse and Mental Health Services Administration.
6706 This will direct the policy lab to issue and review guidance and
6707 grant applicants in the mental health and substance abuse space.

6708 And I will yield back. Are there other members wishing to
6709 speak on the amendment in the nature of a substitute?

6710 Mr. Engel. Yes, Mr. Chairman.

6711 Mr. Burgess. For what purpose does the gentleman from New
6712 York seek recognition?

6713 Mr. Engel. Strike the last word.

6714 Mr. Burgess. The gentleman is recognized for 5 minutes.

6715 Mr. Engel. Thank you, Mr. Chairman. The RESULTS Act, which
6716 I am pleased to have co-introduced with Congressman Stivers, will

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6717 build on the important work we started with the 21st Century Cures
6718 Act. Cures created the National Mental Health and Substance Use
6719 Policy Laboratory with the goal of promoting evidence-based
6720 activities to prevent and treat mental health and substance use
6721 disorders.

6722 The RESULTS Act will help advance that goal. It directs the
6723 policy lab to issue new guidance to applicants seeking federal
6724 funding to treat or prevent mental health or substance use
6725 disorders. This guidance will provide needed clarity to
6726 applicants for federal grants, empowering them to emulate
6727 successful activities in their communities and implement
6728 evidence-based solutions that will help turn the tide of the
6729 opioid crisis. This is a straightforward measure, bipartisan,
6730 and I urge my colleagues to support it. I yield back the balance
6731 of my time.

6732 Mr. Burgess. The chair thanks the gentleman. The
6733 gentleman yields back. Are there other members wishing to be
6734 heard on the amendment to the Stivers bill?

6735 Seeing none, the question now occurs on adoption of the
6736 amendment to H.R. 5272.

6737 Those in favor will signify by saying aye.

6738 Those opposed, no.

6739 In the opinion of the chair, the ayes have it, and the
6740 amendment is agreed to. Is there any member that wishes to be

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6741 recognized on H.R. 5272?

6742 Seeing none, I will recognize myself again for 1 minute. We
6743 heard from our patient and family panel last Thursday, and this
6744 was a direct ask by one of the witnesses who came and spoke with
6745 us. I will admit to that the RESULTS Act was not high on my list
6746 of things for us to consider tonight, but such a passionate plea
6747 was made by one of our witnesses, the CEO of a group called
6748 Shatterproof that is the reason why the amendment was made in order
6749 make the bill ready for this markup, and I appreciate everyone's
6750 work in getting it to that point. And I certainly want to thank
6751 the witnesses who presented data for us last week.

6752 Seeing no other members that wish to speak on the bill, the
6753 question now occurs on forwarding H.R. 5272, as amended, to the
6754 full committee.

6755 All those in favor will signify by saying aye.

6756 Those opposed, no.

6757 The ayes appear to have it. The ayes have it, and the bill,
6758 as amended, is agreed to.

6759 The chair calls up H.R. 5327.

6760 [The bill follows:]

6761

6762 ***** COMMITTEE INSERT 72 *****

6763 Mr. Burgess. Number 18 on the list, and asks the Clerk to
6764 report.

6765 The Clerk. H.R. 5327, to amend Title V of the Public Health
6766 Service Act to establish a grant program to create comprehensive
6767 opioid recovery centers, and for other purposes.

6768 Mr. Burgess. Without objection, the first reading of the
6769 bill is dispensed with. The bill is open for amendment at any
6770 point, so ordered. Are there bipartisan amendments to the bill?

6771 Mr. Guthrie. Mr. Chairman?

6772 Mr. Burgess. For what purpose does the gentleman from
6773 Kentucky seek recognition?

6774 Mr. Guthrie. I would like to call up my amendment in the
6775 nature of a substitute.

6776 [The amendment of Mr. Guthrie follows:]

6777

6778 ***** COMMITTEE INSERT 73 *****

6779 Mr. Burgess. The Clerk will report the amendment.

6780 The Clerk. Amendment in the nature of a substitute to H.R.
6781 5327, offered by Mr. Guthrie.

6782 Mr. Guthrie. Thank you.

6783 Mr. Burgess. The gentleman is recognized for 5 minutes on
6784 the amendment.

6785 Mr. Guthrie. Thank you, Mr. Chairman. This is a bipartisan
6786 amendment and I will speak to the amendment and the underlying
6787 bill. It is a bipartisan amendment offered on behalf of myself
6788 and Ranking Member Gene Green. This amendment reflects technical
6789 changes suggested by HHS technical assistance document. The
6790 changes also ensure family resources are available to those
6791 suffering from substance use disorders. I urge my colleagues to
6792 support this amendment.

6793 I also am proud to sponsor this underlying legislation with
6794 Congressman Gene Green, also Congressman Bucshon, and Congressman
6795 Lujan. The current addiction treatment system in America is
6796 fragmented and composed of a number of types of settings providing
6797 varying degrees of treatment services. Oversight of these
6798 providers range from none to minimal to extensive depending on
6799 the location, type of setting, and form of treatment offered to
6800 patients. Under the Comprehensive Opioid Recovery Act of 2018,
6801 comprehensive opioid recovery centers, or CORCs, would serve to
6802 help fill this need for coordinated, comprehensive continuum of

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6803 care. I urge my colleagues to support the amendment and also the
6804 underlying bill.

6805 And I will yield my time to -- Mr. Green, do you want to use
6806 your own time or -- I yield my time to Mr. Green.

6807 Mr. Green. I thank my colleague and co-sponsor for yielding
6808 to me. I move to strike the last word and speak in support of
6809 an amendment in the nature of a substitute for the Comprehensive
6810 Opioid Recovery Centers Act. This legislation creates a unique
6811 model of patient-centered care designed to address the opioid
6812 crisis. If enactment into law, the Comprehensive Opioid Recovery
6813 Centers Act will provide a full range of treatment options for
6814 patients suffering from opioid addiction or other substance use
6815 disorders.

6816 Designated centers would receive grants in their designation
6817 through SAMHSA and be required to provide a wide range of
6818 evidence-based treatment services as well as recovery support
6819 programs. These services include, but not limited to, all
6820 FDA-approved medications, detoxification, counseling,
6821 residential rehabilitation and recovery housing, community-based
6822 and peer recovery support services and job training, and placement
6823 assistance.

6824 I thank my colleague, Congressman Guthrie, for his hard work
6825 and cooperation on this along with our other co-sponsors and the
6826 House side, both Congressman Bucshon and Congressman Lujan. I

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6827 also want to thank Senator Hassan from New Hampshire and Senator
6828 Capito of West Virginia for introducing a companion bill in the
6829 Senate's package that considered -- and I urge my colleagues
6830 support this, and yield back.

6831 And, Mr. Chairman, one thing, that roundtable we did last
6832 Thursday, I was shocked and we already passed a bill to deal with
6833 some of that, but the number of patients that would go to Florida
6834 and be transferred from center to center, that was not useful.
6835 And so this is something we would hope to have a model recovery
6836 center that would be a one-stop shop, so to speak, and I yield
6837 back my time.

6838 Mr. Burgess. The chair thanks the gentleman and thanks the
6839 gentleman from Kentucky. Are there other members --

6840 Mr. Guthrie. I will yield, some of my time can yield to the
6841 gentleman from New Mexico.

6842 Mr. Burgess. The gentleman is recognized.

6843 Mr. Lujan. Thank you, Mr. Chairman, and thank you, Mr.
6844 Guthrie, and of course, Mr. Bucshon, for working with myself and
6845 my ranking member, Mr. Green, on this bill.

6846 This bill would fund at least ten comprehensive opioid
6847 centers across the country. Now we know ten centers across 50
6848 states will not solve this problem, but we hope that these centers
6849 can stand as an example for what other substance use disorder
6850 facilities could strive to be.

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6851 Mr. Guthrie, I look forward to continuing to work on this
6852 language together.

6853 As we have heard from our witness over the last few weeks,
6854 we cannot call something comprehensive without addressing
6855 prevention. Not only do we need to help families struggling with
6856 substance abuse now, but we need to prevent new families from
6857 becoming victims of this epidemic. It is not enough to simply
6858 treat people already struggling with addiction when we know
6859 prevention is so important and we know prevention is key to not
6860 becoming addicted in the first place. This is where a concerted
6861 effort for prevention services comes in. It is my hope that this
6862 language can be amended before full committee markup to include
6863 a prevention component.

6864 And again I thank my colleagues and all the staff for their
6865 efforts on this bill and I yield back.

6866 Mr. Guthrie. Thank you. I agree we need to look forward
6867 to working together as we move forward. I have 48 seconds if Ms.
6868 Schakowsky would like my time, or if you need more time. I am
6869 happy to yield to you. You are good, okay. Thank you. I look
6870 forward to working with that and I yield back.

6871 Mr. Burgess. The gentleman yields back.

6872 For what purpose does the gentlelady from Illinois seek
6873 recognition?'

6874 Ms. Schakowsky. Thank you, Mr. Chairman. I move to strike

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6875 the last word.

6876 Mr. Burgess. The gentlelady is recognized for 5 minutes.

6877 Ms. Schakowsky. More than commenting on this exact bill,
6878 I just wanted to make a point about another idea. As we are
6879 considering solutions to the opioids crisis, I am concerned about
6880 segmenting our healthcare system and creating opioid-specific
6881 policies. By doing this we ignore the fact that substance use
6882 disorders like alcohol and crack cocaine have ravaged communities
6883 for decades and we have not really put forth the resources to
6884 address them. In fact, in the past we have called them junkies
6885 and criminals and continued to criminalize many addictions rather
6886 than treat the substance abuse disorder.

6887 So I am concerned that creating opioid-specific centers and
6888 not taking into account all of substance abuse disorders, you
6889 know, that that is what we are doing. I believe that the CARE
6890 Act legislation introduced last week by Congressman Elijah
6891 Cummings and Senator Elizabeth Warren is an important proposal
6892 in addressing substance abuse more broadly. The CARE Act is a
6893 comprehensive approach to addressing the opioid epidemic and
6894 substance abuse disorders.

6895 This legislation is modeled directly on the Ryan White Care
6896 Act, which my colleague from Florida has talked a good deal about,
6897 which was passed with bipartisan support almost 30 years ago to
6898 address another pressing public health crisis, the HIV epidemic.

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6899 Sixty four thousand Americans died of drug overdose in 2016, and
6900 as Cathy Castor mentioned that is a figure that rivals the death
6901 toll at the height of the HIV/AIDS epidemic.

6902 The CARE Act would devote real resources to this crisis,
6903 providing \$100 billion over 10 years directly to state and local
6904 areas that are on the front line to pay for treatment for
6905 individuals with substance use disorder. Funding would be
6906 targeted to areas that are hit the hardest by the epidemic.
6907 Competitive grant funding would also be available to states and
6908 counties that need additional resources. Under this bill, my
6909 home state of Illinois would receive nearly \$125 million per year
6910 for prevention, treatment, and support services. Cook County,
6911 which had 2,400 overdose deaths from 2014 to 2016, would receive
6912 \$30.4 million each year.

6913 This bill would provide nearly \$2 billion per year for public
6914 health surveillance, research, and improvement training for
6915 health professionals, and a billion dollars per year to support
6916 innovative service delivery. The bill would direct the federal
6917 government to negotiate lower prices for the opioid overdose
6918 reversal drugs and provide \$500 million per year to districts to
6919 distribute drugs to the states and local entities.

6920 So this is the idea for a really comprehensive approach. The
6921 epidemic doesn't discriminate based on politics. It affects poor
6922 people and middle class people. And it seems the gravity of the

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6923 opioid epidemic demands serious comprehensive response to the
6924 crisis and the CARE Act would provide just that. And I hope that
6925 our committee will consider this approach as we move forward with
6926 our work.

6927 And I thank you and --

6928 Mr. Lujan. Will the gentlelady yield?

6929 Ms. Schakowsky. -- yield if anybody wants a minute.

6930 Yes, to Mr. Lujan.

6931 Mr. Lujan. Thank you very much, Congresswoman Schakowsky.

6932 And I as well share your concern with making sure that we are able
6933 to advocate for full substance use disorder and, as always, always
6934 open to working with you in all of those areas. I share the
6935 concern after visiting with many families and the constituents
6936 that I represent with concern that there is not more conversations
6937 taking place with other substance use disorders, namely the
6938 parents of a son who they lost to alcoholism as well.

6939 And that is why this bill, as well, it allows for full
6940 substance use disorder treatment, alcohol and other substances.
6941 But again, look forward to working with you to see how we might
6942 be able to include that further.

6943 Thank you. I yield back.

6944 Ms. Schakowsky. Thank you and I yield back.

6945 Mr. Burgess. The chair thanks the gentlelady. Is there any
6946 other member wishing to be heard on the amendment in the nature

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6947 of a substitute by the gentleman from Kentucky, Mr. Guthrie?

6948 Seeing none, the question then occurs on adopting the
6949 amendment in the nature of a substitute to H.R. 5327.

6950 Those in favor will signify by saying aye.

6951 Those opposed, no.

6952 In the opinion of the chair, the ayes have it. The ayes have
6953 it, and the amendment is agreed to. Is there further discussion
6954 on H.R. 5327?

6955 Seeing none, it is now, the question now occurs on forwarding
6956 H.R. 5327, as amended, to the full committee.

6957 All those in favor signify by saying aye.

6958 Those opposed, no.

6959 The ayes appear to have it. The ayes have it, and the bill
6960 is agreed to.

6961 It is now in order of the chair calls up H.R. 5329.

6962 [The bill follows:]

6963

6964 ***** COMMITTEE INSERT 74 *****

6965 Mr. Burgess. That is Number 19 on the list, and asks the
6966 Clerk to report.

6967 The Clerk. H.R. 5329, to amend the Public Health Service
6968 Act to reauthorize and enhance the Poison Center national
6969 toll-free number, national media campaign and grant program, and
6970 for other purposes.

6971 Mr. Burgess. Without objection, the first reading of the
6972 bill is dispensed with. The bill is open for amendment at any
6973 point, so ordered. Are there bipartisan amendments to the bill?

6974 Are there other amendments to the bill?

6975 For what purpose does the gentlelady from Indiana seek
6976 recognition?

6977 Mrs. Brooks. I move to strike the last word, Mr. Chairman.

6978 Mr. Burgess. The gentlelady is recognized for 5 minutes to
6979 speak on her bill.

6980 Mrs. Brooks. Thank you, Mr. Chairman. I would also like
6981 to thank my colleagues, Mr. Engel, Mr. Barton, and Ms. DeGette,
6982 for work on this bipartisan bill.

6983 Poison control centers save countless lives, prevent toxic
6984 exposure and poisoning injury, which is actually the leading cause
6985 of injury death in the United States. And I know we don't often
6986 think of opioid overdose as poisoning injury but it is, and it
6987 reduces billions of dollars in unnecessary healthcare costs while
6988 increasing public health awareness. This bill amends the Public

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6989 Health Service Act to reauthorize funding for the poison control
6990 centers toll-free phone number, the national media campaign which
6991 educates the public and healthcare providers about poison
6992 prevention, and reauthorizes the state grant program for an
6993 additional 5 years. It also clarifies that poison centers can
6994 be called upon to assist with public health emergencies, responses
6995 of preparedness, requests that enhanced communication
6996 capabilities like texting be established, and requests that the
6997 FCC work with HHS to ensure that calls to our 1-800 numbers are
6998 properly routed. It ensures that in the future call routing will
6999 be based on the caller's location rather than the individual's
7000 area code and it also extends our nationwide public awareness
7001 campaign with HHS.

7002 Our country is a network of 55 poison control centers that
7003 provide information and emergency services 24/7 every day of the
7004 year. The center receives approximately three million calls
7005 annually over this toll-free number. Since 2011, poison control
7006 centers have handled approximately 500,000 cases of opioid misuse
7007 and abuse, approximately 192 cases per day, every day. In 1 month
7008 alone, they received calls involving 9,039 opioid exposures
7009 reported to poison control centers in just 1 month. Many of the
7010 calls come from first responders and hospital personnel with
7011 education and tools to identify new and emerging drugs of abuse.
7012 I would just urge my colleagues for passage of this incredibly

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7013 important bipartisan bill. The poison control centers offer
7014 tremendous service for our citizens and for families and
7015 individuals who are suffering from the overdose and this is saving
7016 lives when there are overdoses.

7017 And with that I urge my colleagues to support this bill.

7018 Mr. Barton. Will the gentlelady yield?

7019 Mrs. Brooks. Yes, I will yield.

7020 Mr. Barton. Right here, to your right, up here.

7021 Mrs. Brooks. Yes, okay. I will yield to Mr. Barton.

7022 Mr. Barton. I thank the gentlelady from Indiana. I want
7023 to commend her on her leadership on this as well as Diana DeGette
7024 and Congressman Eliot Engel on the minority side. In the past
7025 I have been the lead sponsor on this bill. We have reauthorized
7026 the poison control centers a number of times in this committee
7027 in the last 10 years. I am not aware of anything Mr. Chairman
7028 that is controversial. A little bit of a disagreement about the
7029 authorization level, the bill has historically been authorized
7030 at 30 million and because of some restrictions this authorization
7031 level, I think, is it 24 million? That is something that we are
7032 working on and I support the gentlelady's efforts and hope that
7033 the committee will voice vote this and move it on to full
7034 committee.

7035 And I yield back to Mrs. Brooks.

7036 Mr. Burgess. The chair thanks the gentlelady. The

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7037 gentlelady yields back.

7038 Mrs. Brooks. And I believe there may need to be some
7039 clarification because I believe we are working on a \$31 million
7040 authorization.

7041 Mr. Barton. Oh, good. See, that is why you are the lead
7042 now.

7043 Mrs. Brooks. So I think we are working on a \$31 million
7044 authorization and hopefully we will be able to get this figured
7045 out. And with that I yield back.

7046 Mr. Burgess. The chair thanks the gentlelady. Are there
7047 other members who wish to be heard on the bill?

7048 For what purposes does the gentleman from --

7049 Mr. Engel. Move to strike the last word.

7050 Mr. Burgess. The gentleman is recognized for 5 minutes.

7051 Mr. Engel. Thank you, Mr. Chairman. Most of us already
7052 know about much of the work poison centers do, likely thanks to
7053 a sticker or refrigerator magnet displaying the poison center
7054 phone number. There are 55 poison centers across the United
7055 States available 24 hours a day, 7 days a week, 365 days a year.
7056 They offer real time, lifesaving assistance, and save hundreds
7057 of millions of federal dollars by helping to avoid the unnecessary
7058 use of medical services and shortening the amount of time a person
7059 spends in the hospital, if hospitalization due to poisoning is
7060 necessary.

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7061 But many may not know about the critical role poison centers
7062 are playing in the fight to end the opioid crisis. Since 2011,
7063 U.S. poison centers have handled nearly 200 cases each day
7064 involving opioid misuse. Poison centers have helped detect
7065 trends in the opioid epidemic and experts have educated Americans
7066 about ways they could potentially save the lives of their loved
7067 ones. The Upstate New York Poison Center, for instance, used the
7068 New York State Fair to introduce New Yorkers about proper use of
7069 naloxone, the overdose reversal drug.

7070 The Poison Center Network Enhancement Act, which I have
7071 introduced with Congresswoman Brooks, and let me say I agree with
7072 everything Congresswoman Brooks said before, this would ensure
7073 that these important activities continue. I was proud to
7074 co-author the last poison center reauthorization in 2014, and I
7075 am proud to be a part of this legislation. So I want to thank
7076 Congresswoman Brooks for working with me on this important bill
7077 as well as Congresswoman DeGette and Congressman Barton for being
7078 original co-sponsors.

7079 I urge all of my colleagues to vote for this legislation and
7080 I yield back the balance of my time.

7081 Mr. Burgess. The chair thanks the gentleman. The
7082 gentleman yields back. Are there other members that wish to be
7083 heard on H.R. 5329?

7084 Seeing none, the question then occurs on forwarding H.R. 5329

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7085 to the full committee.

7086 All those in favor will signify by saying aye.

7087 Those opposed, no.

7088 The ayes appear to have it. The ayes have it, and the bill
7089 is forwarded to the full committee.

7090 The chair calls up H.R. 5353.

7091 [The bill follows:]

7092

7093 ***** COMMITTEE INSERT 75 *****

7094 Mr. Burgess. Number 20 on the list, and asks the Clerk to
7095 report.

7096 The Clerk. H.R. 5353, to amend the Public Health Service
7097 Act to reauthorize and expand a program of surveillance and
7098 education carried out by the Centers for Disease Control and
7099 Prevention regarding infections associated with injection drug
7100 use.

7101 Mr. Burgess. Without objection, the first reading of the
7102 bill is dispensed with and the bill is open for amendment at any
7103 point, so ordered. Are there any bipartisan amendments to the
7104 bill?

7105 Mr. Lance. Mr. Chairman?

7106 Mr. Burgess. For what purpose does the gentleman from New
7107 Jersey seek recognition?

7108 Mr. Lance. I have an amendment at the desk.

7109 [The amendment of Mr. Lance follows:]

7110

7111 ***** COMMITTEE INSERT 76 *****

7112 Mr. Burgess. The Clerk will report the amendment.

7113 The Clerk. Amendment in the nature of a substitute to H.R.
7114 5353, offered by Mr. Lance.

7115 Mr. Burgess. Without objection, the reading of the
7116 amendment is dispensed with, and the gentleman from New Jersey
7117 is recognized for 5 minutes in support of his amendment.

7118 Mr. Lance. Thank you, Mr. Chairman, and I want to thank the
7119 principal co-sponsor, Congressman Kennedy, as well as Congressman
7120 Collins, Congresswoman Eshoo, Congressman Barton, and
7121 Congresswoman Matsui.

7122 This amendment strengthens the underlying bill by
7123 incorporating technical assistance provided by the Centers for
7124 Disease Control and other stakeholder groups and will provide the
7125 agency the necessary resources to expand its opiates-related
7126 public health efforts. The amendment clarifies the surveillance
7127 language by including infective endocarditis, a common condition
7128 associated with injection drug use, and viral hepatitis, to ensure
7129 that the CDC can capture hepatitis B and hepatitis C incidence
7130 rates.

7131 A recent guidance issued by the CDC, the name of it is
7132 Managing HIV and Hepatitis C Outbreaks Among People who Inject
7133 Drugs, and this was written in March of this year, provide shocking
7134 statistics that reinforce the importance of public health
7135 surveillance efforts. In 2014, an estimated 1.9 million

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7136 Americans had substance use disorders involving prescription pain
7137 relievers of which 586,000 involved heroin. Heroin injection has
7138 increased 63 percent between 2002 and 2013. Four out of every
7139 five heroin users started by misusing prescription opiates.

7140 The White House Council of Economic Advisors recently
7141 estimated the economic burden of the opiate crisis inclusive of
7142 the value of lost lives to be over \$500 billion. We must do more
7143 to stop the spread of infectious diseases that stem from the opiate
7144 crisis. This is not just about helping those with addiction,
7145 families and children are being exposed to terrible infections
7146 at an alarming rate. The CDC must implement a plan to turn this
7147 tide and combat the public health consequences of these deadly
7148 trends.

7149 This bipartisan effort is to make sure that the CDC has the
7150 tools it needs and that those facing an opioid addiction are
7151 educated for the safety not only of themselves but for their
7152 families. Those who have fallen victim to addiction must be able
7153 to reclaim their lives. Stopping the spread of deadly infections
7154 is one way to make sure that this occurs. The time is now to stop
7155 these infections before more lives are lost.

7156 Thank you, Mr. Chairman, and I yield back the balance of my
7157 time.

7158 Mr. Burgess. The chair thanks the gentleman and the
7159 gentleman yields back. Are there other members that wish to be

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7160 heard on the Lance amendment?

7161 Seeing none, the question then is on the amendment in the
7162 nature of a substitute to 5353.

7163 Those in favor will signify by saying aye.

7164 Those opposed, nay.

7165 In the opinion of the chair, the ayes have it. And the ayes
7166 have it, and the amendment of the nature of a substitute is agreed
7167 to. Are there other members that wish to be heard on the
7168 underlying bill?

7169 Seeing none, the question now occurs on forwarding H.R. 5353,
7170 as amended, to the full committee.

7171 All those in favor will signify by saying aye.

7172 Those opposed, no.

7173 The ayes appear to have it. The ayes have it, and the bill
7174 is forwarded to the committee.

7175 The chair calls up the Committee Print entitled, A Bill to
7176 Enhance and Improve State-run Prescription Drug Monitoring
7177 Programs, Number 21, and asks the Clerk to report.

7178 [The information follows:]

7179

7180 ***** COMMITTEE INSERT 77 *****

7181 The Clerk. Discussion draft to amend the Public Health Service
7182 Act to authorize the Director of the Centers of Disease Control
7183 and Prevention to carry out certain activities to prevent
7184 controlled substances overdoses, and for other purposes.

7185 Mr. Burgess. Without objection, the first reading of the
7186 bill is dispensed with. The bill is open for amendment at any
7187 point, so ordered. Are there bipartisan amendments to the bill?

7188 Are there amendments to the bill?

7189 Does any member wish to be heard on the bill?

7190 For what purpose does the gentleman from Virginia seek
7191 recognition?

7192 Mr. Griffith. Mr. Chairman, I wish to be heard on the bill.

7193 Mr. Burgess. The gentleman is recognized for --

7194 Mr. Griffith. State-run prescription drug monitoring
7195 programs, PDMPs, are widely recognized as an important tool in
7196 fighting the opioid epidemic by enabling providers to better
7197 identify patients who may be at risk for misuse or abuse of opioid
7198 prescriptions. This bill will improve federal support for
7199 state-run PDMPs and enable the Centers for Disease Control to
7200 better collect data that can be integrated into the physician
7201 clinical workflow so that all providers have access to timely and
7202 complete data that they need in order to make the best decision
7203 for their patients. I am pleased to be working with my colleague,
7204 Mr. Pallone, on this important piece of legislation and I yield

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7205 back.

7206 Mr. Burgess. Would the gentleman yield to the gentleman
7207 from Georgia?

7208 Mr. Griffith. I will most happily yield to my friend from
7209 Georgia, Mr. Carter.

7210 Mr. Carter. And thank you.

7211 Mr. Chairman, I appreciate the importance of enhancing the
7212 capabilities of PDMPs and want to thank the sponsors of the bill.
7213 I want to raise my concern with state PDMPs and to potential impact
7214 they have on access to non-opioid, non-narcotic drugs that are
7215 essential to epilepsy patients that are on Schedule V which
7216 subject doctors to having to run a query when prescribing.
7217 Including epilepsy medications in PDMPs could delay access to
7218 treatment that is critical for achieving and maintaining seizure
7219 control. People living with epilepsy who experience a delay in
7220 receiving their medication due to PDMP requirements are at a high
7221 risk for seizures and related complications, including death.
7222 Furthermore, time spent by providers querying and reporting on
7223 scheduled epilepsy medications is time that could be better spent
7224 caring for patients. A number of states have already reduced
7225 query requirements for Schedule V epilepsy medications.

7226 I appreciate and thank the sponsors' work on this issue and
7227 stand ready to help address barriers to accessing medications for
7228 epilepsy patients. And I thank the gentleman for yielding.

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7229 Mr. Griffith. And claiming back my time, I would say to the
7230 gentleman that more than happy to work out a carve-out to take
7231 care of that problem which is why it is so good that we have this
7232 here today so that we can discuss it as a team working together
7233 on both sides of the aisle.

7234 Mr. Pallone. Would the gentleman yield?

7235 Mr. Griffith. I will yield to my colleague from New Jersey.

7236 Mr. Pallone. Thank you. I was the original Democratic
7237 sponsor of NASPR going back to the 107th Congress when I worked
7238 with former Congressman Ed Whitfield to introduce the original
7239 legislation and I have long felt that PDMPs are as public health
7240 tools can prevent and respond to opiate abuse. As the technology
7241 has matured, we have moved from working towards the goal of
7242 maturing the interstate sharing of PDMP data now getting closer
7243 to achieving that in every state, and now we are, you know,
7244 basically trying to make the PDMPs more interconnected in real
7245 time and usable for public health surveillance and clinical
7246 decisionmaking.

7247 So continuing to strengthen PDMPs will improve our ability
7248 to prevent addiction from occurring in the first place and help
7249 identify individuals who could benefit from treatment for opioid
7250 use disorders. So that is why I continue to support efforts to
7251 provide federal funding to states as they continue to enhance
7252 their PDMPs and urge my colleagues to support this legislation.

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7253 I yield back to the gentleman.

7254 Mr. Griffith. And I thank the gentleman for his comments
7255 and his hard work on this issue both now and in the past. And
7256 it looks like we will have all 50 states with a PDMP program of
7257 some sort, but now what we want them to do is to be able to
7258 intercommunicate as the gentleman said.

7259 And with that, Mr. Chairman, I would hope everyone would
7260 support this and send it on to the full committee, and yield back.

7261 Mr. Burgess. The chair thanks the gentleman. The
7262 gentleman yields back. Are there other members wishing to be
7263 heard on the Committee Print?

7264 Seeing none, the question now occurs on forwarding the
7265 Committee Print to the full committee.

7266 All those in favor will signify by saying aye.

7267 Those opposed, no.

7268 In the opinion of the chair, the ayes have it. The ayes have
7269 it, and the bill is agreed to.

7270 The chair calls up Committee Print entitled, A Bill to
7271 Support Peer Support Specialist Workforce, Number 23 on the list,
7272 and ask the Clerk to report.

7273 [The information follows:]

7274

7275 ***** COMMITTEE INSERT 78 *****

7276 The Clerk. Discussion draft to amend the Public Health
7277 Service Act to authorize certain recovery services grants to be
7278 used to establish regional and technical assistance centers.

7279 Mr. Burgess. Without objection, the first reading of the
7280 bill is dispensed with, and the bill is open for amendment at any
7281 point, so ordered. Are there bipartisan amendments to the bill?

7282 Are there other amendments to the bill?

7283 Does anyone wish to be heard on the bill?

7284 For what purpose does the gentleman from New Mexico seek --

7285 Mr. Lujan. Strike the last word, Mr. Chairman.

7286 Mr. Burgess. The gentleman is recognized for 5 minutes.

7287 Mr. Lujan. Thank you, Mr. Chairman. And thanks to Mr.
7288 Johnson of Ohio for being so willing to work with me on this peer
7289 support bill. Anyone who has heard me speak about opioids knows
7290 that I believe strongly that to address this opioid epidemic we
7291 must address our nation's workforce challenges. We have
7292 phenomenal providers in New Mexico and Mr. Johnson has them in
7293 Ohio. But what we both know is that we do not have enough of them.
7294 This is a numbers game, and unfortunately the numbers of people
7295 with substance use disorder far surpass the number of providers
7296 and treatment staff. That is where peer support recovery
7297 specialists come in. For those of you who haven't heard me talk
7298 about this or who did not have the pleasure of hearing from our
7299 witness a few weeks back, peer support recovery specialists are

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7300 people who lived the experience of substance use who have fought
7301 against their addiction and receive training to help others who
7302 are in the midst of their fight now.

7303 Peer support recovery specialists provide immediate and
7304 ongoing support and treatment linkages to individuals in
7305 recovery. As Carlene Deal-Smith, the peer support specialist at
7306 Totah Behavioral Health Authority program in Farmington, New
7307 Mexico, testified, I quote, being able to connect to or patients
7308 both through our shared heritage and shared struggles with
7309 addiction has allowed me to function as a bridge between them,
7310 the staff and the community. This work has enabled me to be
7311 effective as a community support worker and mentor. Most
7312 importantly, I am living proof that recovery can happen, close
7313 quote.

7314 These people provide an incredibly important service to the
7315 community, but peer support programs also mean jobs for
7316 individuals who may not otherwise find jobs. As Ms. Deal-Smith
7317 explained to us, this job got her through hard times in her own
7318 journey with substance use and it made her feel proud to serve
7319 the community and help her people in such an important way. I
7320 am grateful that both the Energy and Commerce Committee and the
7321 Senate Health Committee have acknowledged the importance of these
7322 programs and included our bill in the packages moving forward.

7323 I thank you again, Mr. Chairman, and I yield back.

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7324 Mr. Burgess. The chair thanks the gentleman, and the chair
7325 would recognize that we were only too happy to work on your bill
7326 and Mr. Johnson's bill. It is an important concept and it will
7327 be important in the overall final product.

7328 Are there any other members that wish to be heard on the
7329 Committee Print entitled, A Bill to Support the Peer Support
7330 Specialist Workforce, Number 23 on the list?

7331 Seeing none, the question now occurs on forwarding the
7332 Committee Print to the full committee.

7333 All those in favor say aye.

7334 Those opposed, no.

7335 The ayes appear to have it. The ayes have it, and the bill
7336 is agreed to.

7337 So the current time in the Eastern Time Zone is 9:25, 2125
7338 military time. We have considered 57 bills, and at this point
7339 the subcommittee has concluded our work for today.

7340 Mr. Pallone. Mr. Chairman, would you yield?

7341 Mr. Burgess. For what purpose does the gentleman from New
7342 Jersey seek recognition?

7343 Mr. Pallone. Well, to strike the last word.

7344 Mr. Burgess. The gentleman is recognized.

7345 Mr. Pallone. I don't have it in front of me exactly here,
7346 but it appears that there is several Medicaid bills sponsored by
7347 Democratic members that are on the list. You said 57, we had 63

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7348 or 64. The ones that are remaining that haven't been called up
7349 are all Democratic sponsored bills under the Medicaid title so
7350 -- well, I guess there are some others that are also FDA and public
7351 health. I mean these were noticed amongst this list that we have
7352 had to bear with, you know, for I don't know how many hours here,
7353 9 hours, 10 hours, and I don't understand why we are not bringing
7354 those up. It is only 9:30. It probably wouldn't take more than
7355 another half hour.

7356 What is the reason we are not bringing up the other Democratic
7357 bills that have been noticed which, frankly, I think are at least
7358 as important if not more important in an effort to try to deal
7359 with this opioid epidemic? You guys, the Republicans, are saying
7360 they want to deal with the opioid epidemic. There were a number
7361 of bills that came up that had nothing to do with the opioid
7362 epidemic, and now we are not considering Democratic bills that
7363 clearly do impact the opioid epidemic. So what is the reason we
7364 are not --

7365 Mr. Burgess. Will the gentleman yield?

7366 Mr. Pallone. Yes.

7367 Mr. Burgess. So the bills that are yet to be considered,
7368 they are both Republican and Democratic bills that are yet to be
7369 considered. And as noted previously, the chair does have
7370 discretion in calling up the bills for the subcommittee's
7371 consideration. Bills we have noticed but did not consider are

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7372 bills that are worthy of further discussion. We do think that
7373 additional work is needed on both the Republican and Democratic
7374 bills before we are prepared to advance them to the full committee.

7375 So rather than vote down all of those bills, the best course
7376 of action seems to be to continue the bipartisan discussions,
7377 continue to do the good work that has already been established.
7378 The committee, today, subcommittee, today, has done a significant
7379 amount of work and reported over 50 bills to the full committee.
7380 The hour is late and it is the judgment of your subcommittee chair
7381 that the best course of action is to adjourn for the night and
7382 we will continue to work between now and the time of scheduling
7383 the full committee markup.

7384 Mr. Pallone. Well, Mr. Chairman, if you would yield again,
7385 or I guess it is my time. My concern is that, you know, we are
7386 going to move ahead to full committee with several bills that,
7387 you know, we don't think are ripe or have had enough consideration
7388 discussion and at the same time these other bills, most of if not
7389 all of which are Democratic bills, are not being considered. So
7390 what I would ask, I would ask, A, when do you intend to consider
7391 these in subcommittee, and I would also request that we not move
7392 to full committee with the other bills without considering these
7393 first, if you could respond to that.

7394 Mr. Burgess. Certainly that can be taken under
7395 consideration. There are a number of weeks that are going to

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7396 occur before the full committee markup and there is time to
7397 consider other courses of action. But again as I have stated to
7398 the gentleman previously, rather than have an unfavorable report
7399 on the bills yet to be considered, it is my opinion and the opinion
7400 of others on the committee that it would be better to work toward
7401 getting solutions before we bring those bills up.

7402 Mr. Pallone. Well, Mr. Chairman, again I guess it is my
7403 time. I don't understand. Anyone was free to offer amendments
7404 and were to comment on those bills. If you were the Republicans
7405 on the committee had a problem with those, I think it was incumbent
7406 on you to express those concerns in the same way that the Democrats
7407 did. And if you wanted to offer amendments to offer them --

7408 The Chairman. Would the gentleman yield?

7409 Mr. Pallone. Certainly.

7410 The Chairman. The way on some of these you offered your
7411 response was to vote against them. We didn't think it made sense.
7412 If we vote against them because we don't think they are ready for
7413 full that kills them.

7414 Mr. Pallone. Right, I understand.

7415 The Chairman. So what we would like to do is work with you
7416 going forward. We have passed 57 bills, 48 of them bipartisan
7417 votes, and there is more work to be done. We have been going since
7418 --

7419 Mr. Pallone. Well, reclaiming my time, Mr. Chairman, I

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7420 would just appreciate if this evening before we adjourn you were
7421 to indicate your objections in the same way that we indicated ours.
7422 You know, maybe you could just spend 5 minutes doing that. I would
7423 like to know what the objections are.

7424 Mr. Burgess. But --

7425 The Chairman. Go ahead, Mr. Chairman.

7426 Mr. Burgess. I think we have indicated a willingness to
7427 continue these communications. I will obviously be happy to
7428 share with you the objections I have to some of the bills, but
7429 realistically the Chairman is correct. If they are voted down
7430 at this point it kills those bills and they would not be then
7431 further considered at the full committee.

7432 Mr. Pallone. Well, I just hope, I know my time is running
7433 out, but I would just hope that very soon, hopefully this week,
7434 you will convey to us what the problems are and that we will have
7435 an opportunity to have another markup on those bills before we
7436 move to full committee. You are saying now that the full
7437 committee markup isn't for several weeks, so obviously there would
7438 be time to do that. Thank you.

7439 Mr. Lujan. Mr. Chairman?

7440 Mr. Burgess. Who seeks?

7441 Mr. Lujan. Mr. Chairman?

7442 Mr. Burgess. For what purpose does the gentleman seek
7443 recognition?

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7444 Mr. Lujan. Strike the last word.

7445 Mr. Burgess. The gentleman is recognized for 5 minutes.

7446 Mr. Lujan. Mr. Chairman, one of the bills that we have here
7447 is H.R. 5562 which would require the Secretary of Health and Human
7448 Services to develop a strategy implementing certain
7449 recommendations relating to the Protecting our Infants Act of
7450 2015. It is a bipartisan bill. It is a bill that my office worked
7451 with your office on. As a matter of fact, there is a manager's
7452 amendment that has actually been authored for this particular bill
7453 that takes into consideration the recommendations from this
7454 important report.

7455 I am not certain why it is not being heard tonight. Clearly,
7456 this is a bill that is not just in, it is not in draft form. It
7457 is a bill that we introduced --

7458 The Chairman. Would the gentleman yield?

7459 Mr. Lujan. 1 second, Mr. Chairman.

7460 The Chairman. Right.

7461 Mr. Lujan. I will gladly yield to you, Mr. Chairman.

7462 The Chairman. Yes, I would be happy to engage.

7463 Mr. Lujan. This is a piece of legislation that has been
7464 introduced and actually a manager's amendment by the ranking
7465 member of the House Subcommittee was authored. As far as not
7466 having time to look at, there has been work done here. So I am
7467 confused and not certain why your bill, which is my bill, is not

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7468 coming up.

7469 I would yield to the Chairman of the full committee.

7470 The Chairman. Yes. I know you are confused. That is okay.

7471 We will work with you. I am just kidding.

7472 Look, we have gone since right -- yes, since one o'clock
7473 today. We have heard a lot about too many bills too fast. We
7474 passed through 57, I think, in pretty good order. And these, the
7475 bills that remain some of them have a little controversy to them,
7476 some don't. I think it is a good time to take a break. Let's
7477 work together like we usually do between sub and full or continue
7478 on at sub. The chairman will make those decisions and we move
7479 forward.

7480 I think we have done good work. I commend the chairman and
7481 staffs on both sides. We have worked out a lot of details and
7482 there is more work to be done. We have set a record for the number
7483 of bills that have been considered before this committee, most
7484 likely already, and we will move forward on the others. And so
7485 I know some of them are in discussion draft. We heard a lot about
7486 how we shouldn't move those until they were bills that people
7487 wanted to move and then we did. This is a standard process. We
7488 have gone from one o'clock today until after nine tonight. And
7489 there is important work to do, we don't have to be here all night.
7490 We have more time.

7491 Mr. Burgess. The chairman's observations are extremely

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7492 valid and I do want to thank the staff --

7493 Ms. DeGette. Will the gentleman yield? Will the gentleman
7494 yield?

7495 Mr. Lujan. If I may, it is my time, real quick, Mr. Chairman.

7496 Ms. DeGette. It is Mr. Lujan's time.

7497 Mr. Burgess. There is no time. There is nothing under
7498 consideration.

7499 Mr. Lujan. But Mr. Chairman, you acknowledged me and I have
7500 5 minutes and I yielded to the chairman of the full committee.
7501 So I still have 2-1/2 minutes left.

7502 Ms. DeGette. Now I ask the gentleman to yield to me.

7503 Mr. Lujan. To Chairman Walden, the questions surrounding
7504 the bills tonight that people were rushing into at least were in
7505 draft form. This is a bill that has been introduced that we worked
7506 with the chairman of the subcommittee that the chairman of the
7507 subcommittee has actually authored an amendment, a manager's
7508 amendment, to this bill as well.

7509 I am not -- I am confused, Mr. Chairman. I don't know what
7510 the controversy is here. I would yield to Ms. DeGette.

7511 Ms. DeGette. Well, I know what the controversy is and the
7512 majority doesn't want to say it. So I am going to say it for the
7513 record to put my friends on the other side of the aisle on notice.
7514 This is a bipartisan bill. It is an important bill about
7515 children, about babies being able to get access to treatment, and

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7516 something the underlying bill says is that the HHS standards shall
7517 be implemented. And the HHS standards allow for access for the
7518 mothers of these opioid-addicted babies to get birth control
7519 access.

7520 The chairman's amendment takes out the birth control access
7521 for the women and that is why the majority doesn't want to bring
7522 this bill up tonight because they don't want to have a debate at
7523 9:35 p.m. about women who just gave birth to opioid-addicted
7524 babies access to birth control. It is not abortion. It is not
7525 anything like that. It is about giving women access to birth
7526 control which was recommended by HHS.

7527 Now I am just saying this so I can -- I started my life as
7528 an appellate lawyer and I want to make the record that you are
7529 going to have -- if you try to put this, Mr. Chairman, in the mark
7530 that comes to the full committee, you are going to have a fight
7531 on your hands about birth control and I am going to make sure every
7532 member of this committee has to vote on whether women who give
7533 birth to opioid-addicted babies should have access to birth
7534 control while they get treatment.

7535 Mr. Lujan, I want to thank you for yielding to me. I just
7536 think it is important we put that on the record so everybody has
7537 notice. I am happy to work with the majority on this. I think
7538 we should adopt the HHS regulations in this case and we will have
7539 a bipartisan bill, and I yield back.

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7540 Mr. Burgess. Without objection, the staff is authorized to
7541 make technical and conforming changes to the legislation approved
7542 by the subcommittee today, so ordered.

7543 Without objection, the subcommittee is adjourned.

7544 [Whereupon, at 9:36 p.m., the subcommittee was adjourned.]

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