COMMITTEE ON WAYS AND MEANS

Majority and Minority Staff Report

OPIOID WHITE PAPER:
ANALYSIS OF RESPONSES TO COMMITTEE REQUEST
FOR INFORMATION

April 11, 2018

U.S. House of Representatives
OPIOID WHITE PAPER: 
ANALYSIS OF RESPONSES TO COMMITTEE REQUEST FOR INFORMATION

As a part of the Committee on Ways and Means’ evidence-driven approach to policy, Chairman Brady and Ranking Member Neal, along with Subcommittee on Health Chairman Roskam and Ranking Member Levin, issued a call to stakeholders for best practices and ideas to address the opioid epidemic that is plaguing communities across the nation. The Committee sent a Request for Information (RFI) asking stakeholders to respond to a series of questions about the opioid crisis to help inform future legislative and regulatory policymaking.

The RFI requested feedback on an array of issues pertaining to overprescribing/data tracking, communication and education, and treatment (the original letters are included as an appendix to this report). This white paper combines the responses the Committee received, with a particular focus on legislative solutions within the Committee’s jurisdiction.

Background

The Centers for Disease Control and Prevention (CDC) estimated that more than 42,000 Americans died from opioid-related drug overdoses in 2016 – five times the rate in 1999 and more than any year prior.1 Drug overdoses account for more deaths in America than either falls, guns, or traffic accidents,2 and in 2016, the economic burden from opioids was estimated to be $94 billion.3 The nation is truly facing a public health and law enforcement crisis of historic proportions.

Although overdose rates are highest for people 25 to 54, this public health emergency has had dramatic effects on Medicare beneficiaries.4 According to a study using National Center for Health Statistics Data from 1999 to 2014, Baby Boomers (born between 1947 and 1964) experienced increased risks of death due to prescription opioid overdoses relative to individuals born between 1977 and 1978.5 Within the Medicare program, a July 2017 Department of Health

---

3 Rhyan CN. The potential societal benefit of eliminating opioid overdoses, deaths, and substance use disorders exceeds $95 billion per year. 2017.
and Human Services (HHS) Office of the Inspector General (OIG) report found that one-third of Part D beneficiaries received an opioid prescription in 2016, costing the program $4.1 billion and representing 79.4 million prescriptions. The analysis also found that 501,008 Part D beneficiaries received high amounts of opioids, and 69,563 received “extreme” amounts – many as a result of “doctor shopping,” a practice through which beneficiaries obtain medically unnecessary prescriptions from multiple pharmacies and prescribers.

**Methodology**

The Committee received 110 responses to the RFI, more than half of which came from the provider stakeholder community. The other half of responses came from payers, pharmacy benefit managers (PBM)s/distributors, consumer groups, and other organizations (e.g., medical device and health information technology [HIT] companies). More than half of the respondents also represented association/coalitions with broad membership. Majority and Minority Committee staff reviewed all of the submissions, aggregating findings by theme and focusing primarily on recommendations related to either statutory or regulatory changes within our Committee’s jurisdiction.

**Emergent themes**

The Committee received an array of comments – ranging from the broad to the highly specific – and while we valued all comments we received, the discussion below primarily reflects the concepts and recommendations pertaining to the Committee’s jurisdiction that appeared across a number of RFI respondents. Figure 1 provides a snapshot of the number of stakeholders that provided recommendations to Congress for each major topic.

---

**Figure 1. Count of stakeholder recommendations to Congress, by theme**

---

6 OIG. Opioids in Medicare Part D: Concerns about extreme use and questionable prescribing. 2017.

7 OIG. Opioids in Medicare Part D: Concerns about extreme use and questionable prescribing. 2017.
1. Treatment and reimbursement

The RFI specifically solicited stakeholder feedback on treatment and reimbursement for Medicare services. Thus, a majority of respondents directly addressed these issues, emphasizing the importance of Medicare coverage for evidence-based treatment for opioid use disorders as well as coverage of non-pharmacological pain management techniques that avoid making opioids the default approach. Stakeholders encouraged the Committee and the Centers for Medicare & Medicaid Services (CMS) to develop mechanisms that better support providers delivering non-opioid evidence-based pain management techniques, as well as the beneficiary population suffering from opioid use disorders.

Medication-Assisted Treatment (MAT)

Medicare covers MAT, the evidence-based long-term treatment approach for opioid use disorders that combines medication with counseling and behavioral therapies, if prescribed in an inpatient setting. However, Medicare generally does not cover such medications prescribed or dispensed to patients in an outpatient setting, resulting in coverage gaps for many beneficiaries.

Slightly more than half the respondents expressed support for or directly called on the Committee to enact legislation to expand the use of MAT. Six respondents specifically cited their support for current Committee legislation (i.e., H.R. 4097 – Medicare Beneficiary Opioid Addiction Treatment Act, H.R. 5080 –Combating Opioid Misuse By Advancing Treatment Act, and H.R. 5083 –Expanding Access to Evidence-Based Opioid Treatment for Seniors Act) that expands treatment options under Medicare for individuals with opioid use disorders. Some respondents specifically encouraged the Committee to reimburse MAT through a bundled payment – covering both the counseling and drugs as one unit of payment – under Medicare, as outlined in both H.R. 5080 and H.R. 5083. A number of other respondents encouraged the Committee to add Opioid Treatment Programs (OTPs) as Medicare-certified providers or, more broadly, expand coverage of MAT in outpatient settings.

“Medications to treat chronic opioid use disorder are among the most rigorously researched medications in the world. Study after study has shown that MAT is a highly effective treatment for opioid use disorder.”
– American Association for the Treatment of Opioid Dependence, Inc.

“We recommend Congress …consider opportunities to leverage telemedicine to provide addiction treatment, including MAT for Medicare beneficiaries. In addition to grants, CMS could provide these services through the Medicare program in areas where the opioid crisis is most acute and there is a mental health care professional shortage.”
– Aetna

Commenters found that while the coverage of drugs on an outpatient basis (e.g., buprenorphine) is important, these treatments do not come...
with the ancillary supports needed to help patients address their opioid use disorders. Commenters also recommended the coverage of residential detoxification and residential substance use disorder treatment and incentives to encourage additional practitioners (e.g., nurse practitioners and physician assistants) to become certified to administer MAT. A handful of respondents also discussed the use of telemedicine to deliver opioid use disorder treatment – and MAT specifically – as a way of expanding access to treatment in rural areas.

**Evidence-based non-opioid treatment options**

Studies have demonstrated that a number of non-opioid treatment options (e.g., non-opioid analgesics, acupuncture, physical therapy, etc.) can be just as effective as opioids in treating chronic pain – if not more so. But Medicare and other payers often do not cover these alternatives to the same degree as opioid treatments or may not cover them at all.

Beyond payment for specific treatments, current Medicare policies often create barriers to the adoption of non-opioid treatments. A number of commenters discussed the importance of making these options readily available under Medicare, through increasing coverage, reducing/eliminating beneficiary copays, and increasing reimbursement for such services.

**Reimbursement and quality**

Many commenters agreed that Medicare’s reimbursement/coverage perversely incentivizes opioid prescribing, which may inadvertently lead to overprescribing opioids and undersupply of alternative treatment options – both post-surgery and in the treatment of chronic pain. Several commenters noted that physicians are inadequately compensated for their time screening patients for opioid use disorders, checking state drug monitoring registries, and working with patients to manage their pain. Others suggested that new codes should be developed to reimburse physicians for time spent on activities such as education, counseling, and discussing the full range of pain management options.

---

Stakeholders also urged Congress to work with federal agencies to modernize quality measures across the Medicare program to address addiction screenings, mortality related to opioid use, or pain management after discharge. Similarly, commenters urged Congress to consider policies to prevent the misuse of patient pain-related ratings from CMS patient surveys, including the hospital survey for discharged inpatients under Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS).

2. Tools to prevent overprescribing and abuse

The Committee’s RFI solicited feedback on a range of topics pertaining to overprescribing and data tracking, including e-prior authorization, second-fill limits, and prescription drug monitoring programs (PDMPs). Most respondents directly addressed these requests, many choosing to focus their comments on the importance of widespread use and interoperability of PDMPs and other tools to curb opioid prescribing (although support for various approaches was mixed).

Part D lock-in 11

Only a small number of commenters specifically provided recommendations/suggestions related to CMS’s Part D Lock-In program. These stakeholders recommended Congress work with CMS to ensure that plan sponsors have the ability to: use point-of-sale claim edits to address other frequently abused drugs, including drugs often used concurrently with opioids; assign a beneficiary to a single prescriber without waiting six months as CMS originally proposed; maintain beneficiary locked-in status until receiving provider notification that the member is no longer at risk, rather than limiting lock-in to 12 months as CMS proposed; and allow plans the flexibility to lock-in at-risk beneficiaries that do not precisely match CMS’s criteria.

11 Stakeholder comments were provided before CMS finalized the 2019 Medicare Parts C & D Call Letter on April 2, 2018.
Additionally, commenters suggested CMS require plans to utilize the Lock-In program for at-risk beneficiaries.

**Prescribing limits**

Nearly half of all respondents provided feedback on opioid prescribing limits (e.g., second-fill limits). More so than any other topic, support for prescribing limits was mixed, touching on supply limits, second-fill limits (and exclusions), partial fills, e-prior authorization, and e-prescribing. Respondents were split in their support of duration of supply and second-fill limits, some noting the benefit of such policies and others urging caution that such prescribing restrictions could have unintended consequences for beneficiaries that truly need opioids (e.g., cancer patients or hospice enrollees).

Others suggested that Congress and CMS work with physician groups to develop policies that provide appropriate prescribing guardrails while also ensuring beneficiaries continue to have access to the drugs they need. A few respondents also discussed the need for policies friendly to partial-fills to avoid instances where beneficiaries receive unnecessarily large doses. One stakeholder specifically discussed scenarios where Recovery Audit Contractors (RACs) misidentify partial fills as multiple refills, while another suggested that beneficiaries should not be burdened by full copays for partial fills. Twenty-seven respondents touted the benefits of e-prior authorization and e-prescribing, noting that both have the potential to more effectively facilitate policies around prescribing limits. Four respondents urged Congress to pass H.R. 4841, which standardizes e-prior authorization under Part D.

**Data tracking**

About half of the commenters discussed the challenges of sharing non-standard data across state Prescription Drug Monitoring Plans (PDMPs) and recommended increasing access to data through a variety of methods. PDMPs are state electronic databases that track controlled substance prescriptions; currently 49 states, the District of Columbia, and Guam operate PDMPs, which vary considerably. According to the CDC, these databases “continue to be among the most promising state-level interventions to improve opioid prescribing,” with reported changes in prescribing habits. Stakeholder suggestions included providing every federal health care program access to PDMP data, giving plans access to the PDMP data, developing a national PDMP, and a requiring that prescribers and pharmacists actively check state PDMPs. Without robust access to PDMP data, stakeholders said it is difficult to have a complete picture of prescribed controlled substances. At the very least, commenters said, there is a need for greater interoperability of state-to-state PDMPs and integration with electronic health records.

---

12 Prescription Drug Monitoring Frequently Asked Questions (FAQs). Available at http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq


*Prepared by the Committee on Ways and Means Majority and Minority Staff, April 11, 2018*
3. Screening, education, and communication

The Committee also solicited feedback on screening tools for opioid use disorders and best practices related to both provider and patient education/communication. Broadly, stakeholders emphasized the need for more widespread uptake of screening tools across the continuum of care, as well as the need for increased support for continuing medical education and beneficiary engagement programs.

Screening for opioid use disorders

Commenters underscored the importance of evidence-based risk screening of patients with opioid use disorder or other substance use disorders as part of regular treatment protocols. Comprehensive screening should ideally include a full review of prescribed medications, a review of state PDMPs, and a behavioral health assessment, respondents said. One commenter noted the need to apply appropriate diagnostic criteria for older adults because opioid use disorders can be more difficult to diagnose amid coexisting physical and mental conditions. Additionally, commenters urged hospitals and emergency rooms to adopt these screening methods and integrate education for screening and related treatment protocols for their medical staff. Specifically, some respondents urged broader training and adoption of Medicare’s Screening, Brief Intervention, and Referral to Treatment (SBIRT) services, which are intended to identify at-risk individuals as a preventive measure.

Provider education and communication

Nearly half of the commenters provided recommendations to the Committee around provider education and communication. Such comments were uniformly in favor of increasing provider education in pain management and substance use disorders. Many commenters urged Congress and CMS to support a national educational campaign and continuing medical education programs, and provide more educational resources pertaining to adverse effects of prolonged opioid use and alternative non-pharmacological pain management techniques.

“Physicians and care providers need to identify patients at greater risk for opioid misuse and abuse … along with patients with symptomatic depression and ineffective coping strategies, prior to elective surgery. Physicians, the public, and policy makers should value interventions to lessen stress, improve coping strategies, and enhance support for patients recovering from injury or surgery.”

– American Academy of Orthopaedic Surgeons
Other responses included examples of successful educational endeavors, including developing robust county or state-wide education campaigns; sending notices to outlier prescribers or newsletters intended to educate physicians on best practices for pain management; partnering with medical and professional societies to enhance education and training; and supporting education in local communities through the Extension for Community Healthcare Outcomes (ECHO) project (see sidebar). These commenters urged Congress to look at effective programs and take steps to expand upon those efforts.

Patient education and communication

Many stakeholders also discussed the need for patient education, urging Congress to consider ways to improve patient education across the continuum of care about options for pain management, the adverse effects of prolonged opioid use, and treatment options for substance use disorders. Commenters recommended a range of approaches, including notifying beneficiaries of the risks associated with opioid use at the point of sale and increasing utilization of programs to help engage beneficiaries in their care. Such programs could include substance use disorder coaching, behavioral therapy, pharmacy home programs, peer recovery support services, or adding beneficiaries at-risk of opioid use disorder to the list of core disease conditions as one of the criteria for eligibility into the medication therapy management (MTM) programs (although some respondents expressed concern about this latter step). Some stakeholders called for a nationwide provider and consumer education effort that can help amplify and support provider-to-patient conversations and offer resources to providers, patients, and families.

4. Other issues

Respondents also touched on a range of other issues (many outside the Committee’s jurisdiction), including: repealing the Medicaid Institutions for Mental Diseases (IMD) exclusion; updating the patient privacy regulations in 42 Code of Federal Regulations (CFR) Part 2; funding additional research through the National Institutes of Health, the Agency for Healthcare Research and Quality, and the CDC; and creating a national clearinghouse of orders for controlled substances under the Drug Enforcement Administration. A handful of commenters also urged Congress to consider policies that would encourage proper drug disposal across the continuum of care. Stakeholders recommended Congress encourage greater utilization of medication disposal technologies, develop effective standards and training for proper disposal,
develop reporting requirements when drugs go missing or diversion is suspected/found, and collect comprehensive data on compliance rates with existing disposal requirements.

**Next steps**

The Committee plans to use the findings from stakeholder responses to develop and advance bipartisan policies that focus on improving Medicare’s response to the opioid epidemic. We are hopeful this legislation will touch on many of the stakeholder recommendations, including but not limited to those related to Medicare treatment options/coverage, improving data tracking/prescribing practices, and educating providers and beneficiaries about the risks of long-term opioid use.

*The Committee thanks all the stakeholder organizations for their thoughtful responses to the RFI and looks forward to continuing the dialogue on ways to quickly and effectively respond to this public health emergency.*
As Chairmen and Ranking Members of the Committee on Ways and Means and the Committee’s Subcommittee on Health, following a series of hearings, and as part of our ongoing effort to respond to the opioid crisis, we are seeking feedback from stakeholders across the continuum of care to inform the development of future legislation.

In 2016, more than 42,000 Americans died from opioid-related drug overdoses – five times the rate in 1999, according to the Centers for Disease Control and Prevention (CDC).\(^1\) Drug overdoses kill more Americans than falls, guns, or traffic accidents – and the economic burden from opioids was estimated to be $95 billion in 2016.\(^2\)\(^3\) Though frequently not discussed, the epidemic is particularly problematic for the Medicare population. According to a Department of Health and Human Services (HHS) Office of Inspector General (OIG) report released in July 2017, one-third of Part D beneficiaries received an opioid prescription in 2016, costing the program $4.1 billion and representing 79.4 million prescriptions.\(^4\)

These numbers are unacceptable, and we look forward to partnering with stakeholders such as yourself, as well as the Administration, in this fight against the crisis within the Medicare program.

We ask that you submit this feedback to the questions below by March 15, 2018 by sending a document in Word format to WMOpioidSubmissions@mail.house.gov.

---


\(^3\) Rhyen CN. The potential societal benefit of eliminating opioid overdoses, deaths, and substance use disorders exceeds $95 billion per year. 2017.

\(^4\) OIG. Opioids in Medicare Part D: Concerns about extreme use and questionable prescribing. 2017.
Overprescribing/Data Tracking

1. **Improving the Flow of Information Between the Plans and the Centers for Medicare & Medicaid Services (CMS):** The Committee seeks input regarding the types of information CMS/the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) can provide plans to assist their internal opioid strategies. Additionally, the Committee seeks input on other strategies for streamlining communication between the plans, CMS, and the NBI MEDIC as it relates to opioid overprescribing.

2. **Second-Fill Limits:** The Committee seeks input on types of controls available to plans in the Medicare program to limit second-fill opioid prescriptions for pain management.

3. **Tools to Prevent Opioid Abuse:** The Committee seeks input on tools currently unavailable in the Medicare program that could be used to curb opioid abuse and dependence. The Committee seeks input on best practices and policies that would reduce the use of opioids in emergency departments and other outpatient settings.

4. **Perverse Incentives in Medicare:** The Committee seeks input on perverse incentives within Medicare or other programs that spur overprescribing of opioids across all settings of care, as well as incentives that may provide a barrier to accessing treatment for opioid use disorder.

5. **Medication Therapy Management (MTM):** The Committee seeks input on the value of adding beneficiaries at-risk of opioid use disorder to the list of targeted beneficiaries under the MTM program. Additionally, the Committee seeks input on improvements that could be made to MTM programs to better address coordination of care.

6. **Electronic Prior Authorization:** The Committee seeks input on the value of standardizing the electronic prior authorization process or other improvements that could make electronic prior authorization a more effective tool for providers and plans.

7. **Prescription Drug Monitoring Program (PDMPs):** Currently, CMS does not have access to state PDMPs. The Committee seeks input regarding state PDMP data-sharing with CMS and other health care entities. Specifically, the Committee seeks information on potential barriers to implementation and how plans currently use any information (or would use such information in the future).

Communication and Education

1. **Prescriber Notification and Education:** The Committee seeks input on tactics for notifying “outlier” opioid prescribers. The Committee seeks input on best practices for prescriber education on the adverse effects of prolonged opioid use, clinical guidelines for alternative pain treatments, and clinical guidelines for opioid prescribing.

2. **Beneficiary Notification:** The Committee seeks input on the types of communications that would be appropriate for notification of the adverse effects of prolonged opioid use and alternative treatment options.

Treatment

1. **Opioid Treatment Programs (OTPs) and Medication Assisted Treatment (MAT):** The Committee seeks input on programs and providers plans find most successful for treatment of opioid use disorders. The Committee seeks input on best practices to
promote coordinated and managed care through a bundled payment or otherwise, including for medications such as Methadone, to care of patients suffering from opioid use disorders.

2. Using Alternatives to Opioids for the Treatment of Pain: The Committee seeks input on best practices and policies that would modify prescribing patterns to prevent opioid abuse and misuse and reduce the use of opioids in emergency departments and other outpatient settings. The Committee is interested in ways to effectively address pain and ideas for innovative ways to encourage multimodal treatment of pain through payment reforms or benefit changes.

Thank you for your attention to this matter,

Sincerely,

KEVIN BRADY
Chairman
Committee on Ways and Means

RICHARD NEAL
Ranking Member
Committee on Ways and Means

PETER J. ROSKAM
Chairman
Committee on Ways and Means
Subcommittee on Health

SANDER LEVIN
Ranking Member
Committee on Ways and Means
Subcommittee on Health
As Chairmen and Ranking Members of the Committee on Ways and Means and the Committee’s Subcommittee on Health, following a series of hearings, and as part of our ongoing effort to respond to the opioid crisis, we are seeking feedback from stakeholders across the continuum of care to inform the development of future legislation.

In 2016, more than 42,000 Americans died from opioid-related drug overdoses – five times the rate in 1999, according to the Centers for Disease Control and Prevention (CDC).\(^1\) Drug overdoses kill more Americans than falls, guns, or traffic accidents – and the economic burden from opioids was estimated to be $95 billion in 2016.\(^2\)\(^3\) Though frequently not discussed, the epidemic is particularly problematic for the Medicare population. According to a Department of Health and Human Services (HHS) Office of Inspector General (OIG) report released in July 2017, one-third of Part D beneficiaries received an opioid prescription in 2016, costing the program $4.1 billion and representing 79.4 million prescriptions.\(^4\)

These numbers are unacceptable, and we look forward to partnering with stakeholders such as yourself, as well as the Administration, in this fight against the crisis within the Medicare program.

We ask that you submit this feedback to the questions below by March 15, 2018 by sending a document in Word format to WMOpioidSubmissions@mail.house.gov.

---

3. Rhyen CN. The potential societal benefit of eliminating opioid overdoses, deaths, and substance use disorders exceeds $95 billion per year. 2017.
Overprescribing/Data Tracking

1. **Perverse Incentives in Medicare**: The Committee seeks input on perverse incentives within Medicare that spur overprescribing of opioids across all settings of care. The Committee seeks input on best practices and policies that would modify prescribing patterns to prevent opioid abuse and misuse and reduce the use of opioids in emergency departments and other outpatient settings.

2. **Second-Fill Limits**: The Committee seeks input on issues that may arise from limiting second-fill opioid prescriptions for acute pain.

3. **Tools to Prevent Opioid Abuse**: The Committee seeks input on tools currently unavailable in the Medicare program that could be used to curb opioid abuse and dependence.

4. **Medication Therapy Management (MTM)**: The Committee seeks input on the value of adding beneficiaries at-risk of opioid use disorders to the list of targeted beneficiaries under the MTM program.

5. **Electronic Prior Authorization**: The Committee seeks input on the value of standardizing the electronic prior authorization process and other improvements that could be made to improve coordination and prevent abuse.

6. **Prescription Drug Monitoring Program (PDMPs)**: Currently, CMS does not have access to state PDMPs. The Committee seeks input regarding state PDMP data-sharing with CMS and other health care entities. Specifically, the Committee seeks information on potential barriers to implementation.

Communication and Education

1. **Beneficiary Notification**: The Committee seeks input on the types of communications that would be appropriate for notification of the adverse effects of prolonged opioid use and alternative pain management treatment options.

2. **Prescriber Notification and Education**: The Committee seeks input on the best methods for provider education on the adverse effects of prolonged opioid use, clinical guidelines for alternative pain treatments, and clinical guidelines for opioid prescribing. The Committee also seeks input on effective ways to notify providers who prescribe such medicines in excess of their peers.

Treatment

1. **Opioid Treatment Programs (OTPs) and Medication Assisted Treatment (MAT)**: The Committee seeks input from providers around best practices for identification and referral to OTPs, as well as how an OTP benefit could be integrated into the Medicare fee-for-service program – whether through bundled payments or otherwise. The Committee seeks input on the types of providers that are involved in delivery of MAT, best practices to promote coordinated and managed care, and current reimbursement challenges providers face through Medicaid and commercial plans.

2. **Reimbursement**: The Committee seeks input from providers around resource use and reimbursement issues that should be considered for the Medicare population when expanding treatment options.
3. **Alternative Options for the Treatment of Pain**: The Committee is interested in ways to effectively address pain and ideas for innovative ways to encourage multimodal treatment of pain through payment reforms or benefit changes.

Thank you for your attention to this matter,

Sincerely,

KEVIN BRADY
Chairman
Committee on Ways and Means

RICHARD NEAL
Ranking Member
Committee on Ways and Means

PETER J. ROSKAM
Chairman
Committee on Ways and Means
Subcommittee on Health

SANDER LEVIN
Ranking Member
Committee on Ways and Means
Subcommittee on Health