

Supporting Statement – Part A
Program Integrity Portal FWA Reporting Module - Part D Plans
CMS-10517 (OMB 0938-1262)

Note: This 2020 collection of information request proposes to reinstate – with change – our 0938-1262 control number that was associated with PLATO™ (Predictive Learning Analytics Tracking Outcome) which is no longer operational. PLATO was a web based information platform that was used by the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC). As explained below, the reinstatement is associated with our February 18, 2020 (85 FR 9002) proposed regulatory changes (CMS-4190-P, RIN 0938-AT97).

Background

CMS’s role in overseeing the Medicare program is to ensure that payments are made correctly and that fraud, waste, and abuse are prevented and detected. Failure to do so endangers the Trust Funds and can even result in harm to beneficiaries. CMS has established various regulations over the years to address potentially fraudulent and abusive behavior in the Medicare Parts C and D programs. For instance, 42 CFR 424.535(a)(14)(i) addresses improper prescribing practices and permits CMS to revoke a physician’s or other eligible professional’s enrollment if he or she has a pattern or practice of prescribing Part D drugs that is abusive or represents a threat to the health and safety of Medicare beneficiaries or both.

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The CDC estimated 47,000 overdose deaths were from opioids in 2017, and 36 percent of those deaths involved prescription opioids.¹ On October 26, 2017, Acting Health and Human Services Secretary, Eric D. Hargan, declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.² This public health emergency has since been renewed several times by Secretary Alex M. Azar II³.

Serving as the 60-day notice our proposed rule (CMS-4190-P, RIN 0938-AT97) published in the Federal Register on February 18 (85 FR 9002). The proposed collection of information requirements are intended to aid in the more efficient identification, and prevention of Medicare Part C and D fraud, waste, and abuse. The Program Integrity Portal would collect the data elements for Medicare Part D as specified in proposed § 423.504(b)(4)(vi)(G)(4) through (6).

A. Justification

1. Need and Legal Basis

CMS has a need to better identify drug diversion and enhance the detection and prevention

¹ <https://www.cdc.gov/drugoverdose/data/index.html>.

² <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

³ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-19apr2019.aspx>

of fraud, waste and abuse in the Medicare Part D program. In order to ensure the protection of the Medicare Trust Fund, CMS contracts and works with our program integrity contractors (the NBI MEDIC and the I-MEDIC) to support CMS' audit, oversight and antifraud and abuse efforts associated with the Medicare Advantage (MA /Part C) and Prescription Drug (Part D) programs. As stated at 422.503(b)(4)(vi)(G)(3) and 423.504(b)(4)(vi)(G)(3), plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs, respectively, to CMS or its designee. CMS plans to utilize a module within the Health Plan Management System (HPMS) as a program integrity portal for information collection and dissemination. The Health Plan Management System (HPMS) is a web-enabled information system that serves a critical role in the ongoing operations of the Medicare Advantage (MA) and Part D programs. HPMS services the MA and Part D programs in two central ways. First, HPMS functionality facilitates the numerous data collection and reporting activities mandated for these entities by legislation. Second, HPMS provides support for the ongoing operations of the plan enrollment and plan compliance business functions as well as for longer-term strategic planning and program analysis.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) (Public Law 115-271) was signed into law on October 24, 2018. Section 6063 of the SUPPORT ACT requires HHS to establish a secure web-based program integrity portal (or other successor technology) that would allow secure communication among the Secretary, MA and Part D plan sponsors, as well as eligible entities with a contract under section 1893, such as Medicare program integrity contractors. The program integrity portal would serve as the core repository for the data addressed in sections 2008 and 6063 of the SUPPORT Act. These provisions of the SUPPORT Act require Part D plan sponsor to have procedures to identify, and must report to CMS or its designee either of the following: any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act; and any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan. The required data shall be submitted via the program integrity portal. In addition, the plans may report a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste and abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners.

Such data and the regular submission and dissemination of this important information would strengthen CMS' ability to oversee plan sponsors' efforts to maintain an effective fraud, waste, and abuse program. Data sharing via use of a portal would, in conjunction with our proposals, help accomplish the following objectives in our efforts to alleviate the opioid epidemic: enable CMS to perform data analysis to identify fraud schemes; facilitate transparency among CMS and plan sponsors through the exchange of information; provide better information and education to plan sponsors on potential fraud, waste, and abuse

issues, thus enabling plan sponsors to investigate and take action based on such data; improve fraud detection across the Medicare program, accordingly allowing for increased recovery of taxpayer funds and enrollee expenditures (for example, premiums, co-insurance, other plan cost sharing); provide more effective support, including leads, to plan sponsors and law enforcement; increase beneficiary safety through increased oversight measures.

The program integrity provisions throughout the Affordable Care Act of 2010 (ACA), and particularly in Title VI, outline expectations for proactive detection and prevention of fraud, waste, and abuse, as well as robust program management, performance measurement, and reporting.

Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 108-173) was signed into law on December 8, 2003. The MMA established a new voluntary outpatient prescription drug benefit under Part D of Title XVIII of the Social Security Act (the Act). The prescription drug benefit, referred to as Medicare Part D, as well as an employer subsidy for qualified retiree health plans, began on January 1, 2006.

The final rule implementing the Medicare Prescription Drug Benefit published in the Federal Register on January 28, 2005 (70 FR 4193).

The Patient Protection and Affordable Care Act (P.L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act (P.L. 111-152) was enacted on March 30, 2010 and modified a number of Medicare provisions in P.L. 111-148 and added several new provisions. The Patient Protection and Affordable Care Act (P.L. 111-148) and the Health Care and Education Reconciliation Act (P.L. 111-152) are collectively referred to as the Affordable Care Act of 2010 (ACA). The ACA includes significant reforms of the private health insurance industry as well as the Medicare and Medicaid programs. The ACA strengthens program integrity efforts across Medicare, including Part C (Medicare Advantage) and Part D (Prescription Drug) programs.

2. Information Users

CMS, Program Integrity Contractors, Medicare Parts C and D plan sponsors, and law enforcement will be able to review national summary data and actions taken against providers. Medicare Advantage and Prescription Drug Plans will be required to submit information related to fraud, waste and abuse as specified in CMS-4190-P.

3. Use of Information Technology

The Program Integrity Portal that will be utilized via HPMS is 100% electronic, as the site for collecting the data is web-based.

*To comply with the Government Paperwork Elimination Act (GPEA), you must also include the following information in this section:

- *Is this collection currently available for completion electronically?*

Yes, all information is electronic.

- *Does this collection require a signature from the respondent(s)?*

No, a signature is not required from the respondents.

- *If CMS had the capability of accepting electronic signature(s), could this collection be made available electronically?*

Yes, this collection could be made available electronically.

- *If this collection isn't currently electronic but will be made electronic in the future, please give a date (month and year) as to when this will be available electronically and explain why it can't be done sooner.*

Not applicable. The collection tool is entirely electronic.

- *If this collection cannot be made electronic or if it isn't cost beneficial to make it electronic, please explain.*

Not applicable. The collection tool is entirely electronic.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Program Integrity portal will provide smaller plan sponsors with data that will assist with oversight of fraud, waste and abuse.

6. Less Frequent Collection

The information will be collected as specified in CMS-4190-P. This data collection is to aid in the more efficient identification, and prevention of Medicare Part C and D fraud, waste, and abuse.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that

- are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

Serving as the 60-day notice, the proposed rule (CMS-4190-P, RIN 0938-AT97) filed for public inspection on February 5, 2020 and published on February 18 (85 FR 9002). Comments are due by April 6, 2020.

9. Payments/Gifts to Respondents

No payment or gifts to respondents. The information provided is complimentary to PartD plan sponsors, program integrity contractors and law enforcement.

10. Confidentiality

Information will be confidential except as required under CMS-4190 P- communication and sharing of information with related entities The Program Integrity Portal is specific to data for an individual contract. The Secretary must make available to the plans, not less frequently than quarterly, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. Although the national summary data described above will be shared, the information must be anonymized data submitted by plans without identifying the source of such information.

11. Sensitive Questions

There are no questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

As noted in this section and in section 15 of this Supporting Statement, our updated burden estimates reflect changes in statute and in our operations.

Wage Estimates

To derive average costs we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2018 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent

of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Management Analyst	13-1111	45.38	45.38	90.76

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Our wage and cost estimates assume that a management analyst would be the typical staff person who would be involved in collecting and or reporting the required data.

Collection of Information Requirements and Associated Burden Estimates

The source for the following burden estimates is a pilot program that the Agency initiated in December 2016 with six plan sponsors to test the effectiveness of mandatory reporting of fraud, waste and abuse.

Based on the results of the pilot study, we estimate it would take 247 hours at \$90.76/hr for a management analyst to fulfill the proposed reporting and procedure preparation in the first year. If every plan reported we estimate a first year burden of 15,561 hours (63 plans x 247 hr/plan) at a cost of \$1,412,316 (15,561 hr x \$90.76/hr). The first-year costs consist of the time and effort needed to prepare the procedures and report the inappropriate prescribing information.

In subsequent years, we estimate an annual burden of 9,828 hours (63 plans x 156 hr/plan) at a cost of \$891,989 (9,828 hr x \$90.76/hr). Subsequent effort consists solely of the ongoing time and cost to report the inappropriate prescribing information to CMS.

We cannot anticipate how many plans will need to report any payment suspension to pharmacies in the plans' network or information on inappropriate opioid prescribing to CMS.

Summary of Proposed Burden Estimates

Provision	Regulatory Citation	Number of Respondents	Total Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost in 1 st Year (\$)	Total Cost in Subsequent Years (\$)
Fraud & Abuse Pt D; Initial Year	§ 423.504(b)(4)(vi)(G)(4)	63	63	247	15,561	90.76	1,412,316	N/A
Fraud & Abuse Pt D: Subsequent Years	§ 423.504(b)(4)(vi)(G)(4)	63	63	156	9,828	90.76	N/A	891,989
TOTAL			126	varies	25,389	90.76	1,412,316	891,989

Collection of Information Instruments and Instruction/Guidance Documents

The Program Integrity Portal will collect the data elements for Medicare Part D as specified in the proposed rule CMS-4190-P. The data elements can be found in 42 CFR 423.504(b)(4)(vi)(G)(4) through (6).

13. Capital Costs

There are no foreseen capital costs to respondents as they are not requested to record or store information that is collected. The Program Integrity Portal is a web-based tool in HPMS for Part D plan sponsors, program integrity contractors and law enforcement. The Part D plan sponsors will already possess the necessary equipment, such as computer and Internet access.

This will give them the advantage of obtaining national data without any capital costs to them.

14. Cost to Federal Government

CMS contractor will develop a Program Integrity Portal in the Health Plan Management System that will be used by organizations to report fraud, waste and abuse and used by CMS to track and analyze suspected fraud, waste and abuse activity in Medicare Advantage and Prescription Drug Programs. The procurement cost to develop the module in HPMS and determine the business requirements for the system was \$1,000,000. While there will be operation and maintenance costs once the system is operational, those costs have not been specified prior to production.

15. Changes to Burden

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platform that was used by the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC). The reinstatement is associated with our February 18, 2020 (85 FR 9002) proposed regulatory changes (CMS-4190-P, RIN 0938-AT97) which reflect the planned program integrity portal and the new data required in the proposed regulation

The source for our updated estimates is a pilot program that the Agency initiated in December 2016 with six plan sponsors to test the effectiveness of mandatory reporting of fraud, waste and abuse. The pilot program collected all external or internal Medicare complaints and referrals submitted to the plan's Special Investigations Unit (SIU). The data collected as part of the pilot program was time limited, but broader than the scope of reporting required by sections 2008 and 6063 of the SUPPORT Act. The scope of that pilot tested the reporting of all types of health care fraud, waste, and abuse that the plan sponsors could encounter in their operations and, therefore, could be utilized as a reasonable estimate of burden involved with the quarterly plan reporting to CMS that CMS will use to implement sections 2008 and 6063 of the SUPPORT Act. The pilot program analyzed information that was reported from five of six plan participants on time spent collecting three quarterly data submissions.

Utilizing the pilot as a basis for the burden calculation, it should be noted that a higher level of effort (plan burden) was required for the first data submission as plan sponsors became familiar with the data fields and mapped their data. However, the following data submissions required a significantly reduced level of effort. The first year as previously shown reflects that higher level of effort, 247 hours per plan. For each future year, the estimate is shown at 156 hours per plan.

We would note that the updated estimates of cost assumed that a management analyst (BLS Occupational title 13-1111) would be the typical staff person who would be involved in collecting and or reporting the required data. The total compensation for this occupation was higher than the rate for the occupation which the previous PRA estimate relied upon – the occupation of compliance officer. This assumption reflected the limited information we requested from plans on that subject during the pilot program. It is also important to note that the total number of Part D plans in 2020 (63) was determined through a review of HPMS; the total number excludes PACE plans who are not required to report via HPMS.

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TOTAL			126	varies	25,389	90.76	1,412,316	891,989

16. Publication/Tabulation Dates

Not applicable. No information will be published.

17. Expiration Date

CMS does not have any objection to displaying the expiration date. The Program Integrity Portal application website will display the OMB approval number and the expiration date for the OMB approval.

18. Certification Statement

Not applicable.