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Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D

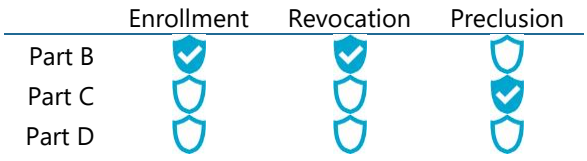
Why This Issue Is Important

Medicare Part D paid $168 billion for drugs for 46.8 million Medicare beneficiaries in 2018. Despite its size, Part D does not have the same protections against pharmacy fraud that other parts of Medicare have. The Office of Inspector General (OIG) has longstanding concerns about pharmacy-related fraud and inappropriate billing in Part D. This issue brief is another step in OIG's larger strategy to fight this fraud and protect beneficiaries. It focuses on the lack of three key tools to safeguard Part D: enrollment, revocation, and preclusion (see Key Takeaways box).

The Issue and Its Impact

To safeguard Medicare against fraud and inappropriate billing, it is crucial to keep out providers—including pharmacies—that pose risks to the program. However, CMS's three key tools for doing so—enrollment, revocation, and preclusion—apply to pharmacies only when they bill Parts B or C, not when they bill Part D.

Key Tools To Protect Medicare From Pharmacy Fraud



Key Takeaways

- Part D does not have three key tools to protect against pharmacy fraud that are available in other parts of Medicare: pharmacy enrollment, revocation, and preclusion.
- Pharmacies must **enroll** in Medicare to bill Part B, but they are not required to enroll to bill Part D.
- Pharmacies that have their enrollment **revoked** for failing to meet Medicare requirements are still allowed to bill Part D.
- **Preclusion**—a new tool that CMS uses to prevent problematic pharmacies from billing Part C—is not used to address problematic pharmacies in Part D.
- CMS should apply the key oversight tools of enrollment, revocation, and preclusion to pharmacies billing Part D.

Pharmacies must enroll in Medicare to bill Part B, but they are not required to enroll to bill Part D. Pharmacies that have their enrollment revoked for failing to meet Medicare requirements are still allowed to bill Part D. CMS adds certain pharmacies that pose risks to Medicare to a Preclusion List. CMS uses preclusion to prevent Part C from paying these pharmacies, but not to prevent Part D from paying them.

How To Fix This Issue

If the powerful oversight tools of enrollment, revocation, and preclusion were available to Part D, CMS could take direct action against pharmacies that pose risks to the Medicare program or beneficiaries. OIG views enrollment, with its screening process, as an extremely effective way to protect the Medicare program, including Part D. We continue to recommend that CMS require pharmacies that bill Part D to enroll in the Medicare program. This was an integral part of a previous recommendation that CMS has yet to implement. We also recommend that CMS allow revocation of Medicare enrollment for inappropriate billing of Medicare Part D and include on the Preclusion List pharmacies that inappropriately bill Part D. Lastly, we recommend that CMS apply the Preclusion List payment prohibition to pharmacies and other providers that dispense Part D drugs. CMS concurred with all three of our new recommendations.

Primer on Key Program Safeguards and Pharmacy Billing

Key Safeguards Against Providers That Pose Risks

- **Enrollment:** The Medicare enrollment process helps ensure that unqualified and potentially fraudulent providers do not bill Medicare. Broadly, the enrollment process entails the provider's completing an application and demonstrating that it meets enrollment requirements. The provider is screened, and its application is then approved, rejected, or denied. If its application is approved, the provider must revalidate its enrollment application every 3 or 5 years.

- **Revocation:** CMS may revoke a provider's Medicare enrollment for a number of reasons, such as the provider's misusing its billing number or abusing its billing privileges (e.g., allowing someone else to use its billing number or submitting claims for deceased beneficiaries). Depending on the reason for revocation, a provider may be subject to a "reenrollment bar," which generally prohibits it from re-enrolling in Medicare for up to 10 years.[1]

- **Preclusion:** Since 2019, CMS has been able to preclude providers from billing Medicare Part C under certain circumstances by placing them on its Preclusion List.[2] Providers may be placed on the list if they are currently revoked from Medicare, are under an active re-enrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

Pharmacy Billing in Different Parts of the Medicare Program

- **Part D (Prescription Drug Coverage):** Part D helps cover the cost of prescription drugs. CMS contracts with private insurance companies—called Part D sponsors—to provide drug coverage under Part D. These sponsors develop pharmacy networks by contracting with different types of pharmacies, such as retail and long-term care pharmacies. In order to bill for prescription drugs under Part D, a pharmacy contracts with a Part D sponsor. Note that some Part D plans are offered by Medicare Advantage plans. These plans are known as Medicare Advantage-prescription drug (MA-PD) plans.

- **Part B (Medical Insurance):** Part B helps cover the cost of services from doctors and other health care providers, outpatient care, home health care, durable medical equipment, and many preventive services (e.g., flu shots). To bill for items and services under Part B, a pharmacy must enroll in Medicare. For example, to bill Part B, a pharmacy may enroll as a supplier of durable medical equipment.

- **Part C (Medicare Advantage):** Part C provides an alternative way for beneficiaries to get Medicare coverage. Medicare Advantage Plans—which are offered by private companies—cover Medicare Part A services (e.g., hospital and nursing home services) as well as Part B items and services. To bill for items and services under Part C, a pharmacy contracts with a Medicare Advantage plan. The pharmacy is not required to enroll in Medicare to bill Part C.

RESULTS

To safeguard Medicare against fraud and inappropriate billing, it is crucial to keep out providers—including pharmacies—that pose risks to the program. CMS has three key tools to prevent or stop providers from participating in Medicare: enrollment, revocation, and preclusion. However, these tools apply to pharmacies when they bill Parts B and C, but not when they bill Part D. Specifically, enrollment in Medicare is required of all pharmacies that bill Part B, and CMS can revoke this enrollment if a pharmacy bills Part B inappropriately. CMS can add a pharmacy to the Preclusion List if it finds that a pharmacy's conduct is detrimental to the Medicare program. This safeguards Part C, as CMS prohibits Part C plans from paying pharmacies that are on the Preclusion List. Enrollment, revocation, and preclusion do not apply to pharmacies when they bill for Part D drugs. Despite the size of Part D, CMS does not have these three key oversight tools to safeguard it from pharmacy fraud and inappropriate billing. In 2018, total spending for Part D drugs was $168 billion.[3]

Pharmacies must enroll in Medicare to bill Part B, but they are not required to enroll to bill Part D

Pharmacies must enroll in Medicare to bill Part B. In contrast, pharmacies are not required to enroll in Medicare to bill Part D. As a result, pharmacies can bill Part D without being screened by CMS or going through the Medicare enrollment application process.[4]

Most pharmacies that bill Part D (76 percent) also bill Part B and therefore are screened by CMS because of their Part B billing. However, their enrollment gives CMS no authority to take action against the pharmacies if there are concerns about their Part D billing. Thus, even if these pharmacies are screened by CMS as part of their enrollment, CMS cannot directly address inappropriate Part D billing by these pharmacies if it occurs.

Pharmacies must enroll in Part B to bill for durable medical equipment and the drugs used with this equipment, such as nebulizers and nebulizer medications, respectively. They must also enroll to bill Part B for some outpatient drugs, such as certain oral cancer and immunosuppressant drugs, as well as to bill for certain immunizations, such as the influenza vaccine.[5]

As part of the enrollment process, CMS screens each pharmacy to ensure that it meets certain requirements. See Exhibit 1. CMS then monitors enrolled pharmacies on an ongoing basis. If an enrolled pharmacy bills Part B inappropriately or is the subject of other concerns about fraud, waste, or abuse in Part B, CMS has the authority to take direct action against it.

Unlike in Part B, a pharmacy does not need to enroll in Medicare to bill Part D. To bill Part D, a pharmacy contracts with a Part D sponsor.[6] A Part D sponsor is required to contract with any willing pharmacy that meets the sponsor's standard terms and conditions.

Exhibit 1: Key Enrollment Requirements for Pharmacies To Bill Part B

The pharmacy must:

- ✓ provide proof of a National Provider Identifier (NPI) and practice location;
- ✓ provide documentation of all applicable Federal and State licenses and certifications; and
- ✓ be operational and able to furnish Medicare covered items or services.

Almost a quarter of all pharmacies (16,721 of 69,922 pharmacies) that bill Part D are not enrolled in Medicare. Among these are pharmacies that CMS has identified as being "high risk" for the program. Specifically, 42 percent of high-risk pharmacies that bill Part D are not enrolled in Medicare.[7] High-risk pharmacies have aberrant Part D billing patterns that warrant additional scrutiny. CMS designates certain retail pharmacies as high risk based on its proactive data analysis.

There is no requirement that high-risk pharmacies be screened by CMS or enrolled in Medicare before they bill Part D in the way that all pharmacies that bill Part B are screened and enrolled.

High-risk pharmacies are more likely than retail pharmacies in general not to be enrolled in Medicare. As noted earlier, 42 percent of high-risk pharmacies are not enrolled, compared to 22 percent of all retail pharmacies that bill Part D.[8] In 2017, Part D paid nearly $1.4 billion to high-risk pharmacies that were not enrolled.

42 percent

of high-risk pharmacies that bill Part D are not enrolled in Medicare

There are other types of pharmacies that are also more likely to not be enrolled in Medicare. Almost half of all long-term care pharmacies (48 percent) and mail-order pharmacies (45 percent) that bill Part D are not enrolled in Medicare. Also, independent pharmacies are much more likely than chain pharmacies to not be enrolled. Fifty-two percent of independent pharmacies are not enrolled, compared to just 4 percent of chain pharmacies.

Pharmacies that have their enrollment revoked for failing to meet Medicare requirements are still allowed to bill Part D

If CMS determines that a pharmacy no longer meets program requirements, it may revoke the pharmacy's enrollment in Medicare.[9] The pharmacy then is prohibited from billing Part B. However, the pharmacy is not prohibited from billing Part D, as the revocation has no effect on Part D billing.

In 2017, a total of 462 pharmacies that billed Part D had their Medicare enrollment revoked. Almost all of these pharmacies—441 of the 462—continued to bill Part D after their revocation. In total, they billed Part D $655 million in 2017 after their enrollment in Medicare was revoked.

The reasons that these pharmacies were revoked ranged from pharmacies' not meeting certain program standards to pharmacies' not being operational. Other reasons included pharmacies' misusing their Medicare billing numbers or abusing their billing privileges.

The following are examples of pharmacies that continued to bill Part D in 2017 after their enrollment was revoked:

- A California pharmacy's Medicare enrollment was revoked because CMS determined that the pharmacy was no longer operational. This pharmacy was also under a re-enrollment bar in 2017 and could not reapply for enrollment for 2 years.[10] Part D paid this pharmacy $2.7 million in 2017 after its enrollment was revoked.

- A New Jersey pharmacy had its enrollment revoked for misusing its Medicare billing number. (Examples of misusing a billing number are knowingly selling the number or allowing another entity to use it.) Part D paid this pharmacy almost $2 million in 2017 after its enrollment was revoked.

- A Florida pharmacy had its enrollment revoked for abusing its Medicare Part B billing privileges. (An example of an abuse of billing privileges is submitting claims for Medicare services that could not have occurred, such as a claim for an office visit with a deceased beneficiary.) Part D paid this pharmacy about $940,000 after the revocation.

Medicare regulations list specific reasons why CMS may revoke a provider's enrollment.[11] CMS does not consider inappropriate Part D billing as a reason to revoke and does not revoke Medicare enrollment for inappropriate Part D billing. Therefore, a pharmacy that inappropriately bills Part D is still allowed to bill Part B.

CMS can use preclusion to prevent Part C from paying pharmacies but not to prevent Part D from paying pharmacies

Preclusion is a new tool that CMS began using in 2019. CMS maintains a list—the Preclusion List—of providers that pose an elevated risk to beneficiaries and the Medicare program. This includes pharmacies.

CMS prohibits Part C plans from paying pharmacies on the Preclusion List.[12] However, the Preclusion List does not apply to pharmacies' billing of Part D; CMS does not prohibit Part D sponsors from paying pharmacies on the Preclusion List.[13] Even Part D plans that are part of Part C plans (i.e., MA-PD plans) are not prohibited from paying pharmacies on the Preclusion List for Part D drugs.

Exhibit 2: Preclusion List

CMS can place a pharmacy on the Preclusion List if the pharmacy:

- is currently revoked from Medicare, is under an active re-enrollment bar, and
- CMS has determined that the underlying conduct that led to the revocation is detrimental to the Medicare program.

Instead, CMS has stated that it expects Part D sponsors to terminate their contracts with precluded pharmacies, but CMS has been clear that this is not a requirement.[14] As a result, pharmacies that pose a known risk to beneficiaries and the program are allowed to bill Part D.

In addition, CMS does not place pharmacies on the Preclusion List for billing Part D inappropriately. CMS may place a pharmacy on the Preclusion List when CMS revokes a pharmacy's enrollment and determines the pharmacy has engaged in behavior that is detrimental to Medicare.[15] See Exhibit 2. However, as noted earlier, CMS does not consider inappropriate Part D billing as a reason to revoke a provider's enrollment. In a few limited circumstances, CMS also may place a pharmacy on the Preclusion List when the pharmacy is not enrolled but poses a risk to the program.[16] However, these circumstances do not include inappropriately billing Part D.

Instead, CMS relies on plan sponsors to identify Part D program integrity issues and to take action as needed against pharmacies in their respective plans. Sponsors are not currently required to inform CMS or other sponsors about most actions they have taken or about concerns they have about specific pharmacies.[17] As a result, a pharmacy that has been identified by one sponsor as detrimental to the Part D program may continue to bill Part D in other sponsors' plans. The pharmacy also can continue to bill Parts B and C, as CMS has no authority to revoke the pharmacy's enrollment or put the pharmacy on the Preclusion List if it inappropriately bills Part D.

Pharmacies can be **precluded** from Part C and **still be billing** Part D

CONCLUSION AND RECOMMENDATIONS

OIG's body of work has highlighted the continuing problems of pharmacy fraud and inappropriate billing, particularly in relation to the opioid crisis.[18] This issue brief demonstrates that, despite its size, Part D does not have the same protections against pharmacy fraud that other parts of Medicare have. These tools—enrollment, revocation, and preclusion—would be critical in safeguarding Part D against pharmacy fraud and inappropriate billing.

CMS currently can use these powerful oversight tools to prevent or stop pharmacies from participating in Parts B and C, but not in Part D. Pharmacies must enroll in Medicare to bill Part B, but they are not required to enroll to bill in Part D. Pharmacies that have their enrollment revoked for failing to meet Medicare requirements are still allowed to bill Part D. Further, CMS can use preclusion to prevent Part C from paying pharmacies but not to prevent Part D from paying pharmacies.

As enrollment, revocation, and preclusion are not applicable to pharmacies when they bill Part D, they do not protect it from pharmacy fraud or inappropriate billing. If these tools were available to Part D, CMS could take direct action against pharmacies when needed and stop Medicare payments to pharmacies that are detrimental to the program.

OIG views enrollment, with its screening process, as an extremely effective way to protect the Medicare program, including Part D. In a 2018 report, OIG recommended that CMS require all Part C and Part D providers and pharmacies to enroll in Medicare.[19] While we continue to recommend that CMS require all Part C and D providers and pharmacies to enroll, we reiterate an integral part of that unimplemented recommendation—namely, that CMS should:

- **Require pharmacies that bill Part D to enroll in the Medicare program**

  Having no enrollment requirement for pharmacies that bill Part D creates a vulnerability to Medicare. Without this requirement, CMS cannot use the enrollment screening process or its revocation authority to safeguard the Part D program from pharmacy fraud and inappropriate billing. This requirement would help ensure that CMS could screen all pharmacies before they provide drugs to Part D beneficiaries. Given the opioid crisis, these safeguards are critical to protecting the program and beneficiaries.

Beyond requiring pharmacy enrollment, there are additional steps CMS should take to safeguard Part D. These steps would help ensure that Part D and other parts of the Medicare program are protected from pharmacies that have engaged in fraud and inappropriate billing. CMS should:

- **Allow revocation of Medicare enrollment for inappropriate billing of Part D**

  CMS does not currently revoke Medicare enrollment for inappropriate billing of Part D. CMS should make the changes necessary to ensure that when a pharmacy inappropriately bills Part D, CMS has the authority to revoke the pharmacy's enrollment. This would promote compliance in Part D and better safeguard other parts of the Medicare program.

  To do this, CMS should assess whether it can use its existing authority to revoke Medicare enrollment for abuse of billing privileges or if it needs to expand the reasons it may revoke Medicare enrollment to specifically include inappropriate billing of Part D. Once CMS establishes its authority, CMS should revoke the enrollment of pharmacies that have billed Part D inappropriately.

- **Include on the Preclusion List pharmacies that inappropriately bill Part D**

  Under current law, CMS may place a pharmacy on the Preclusion List if the pharmacy's enrollment is revoked and its conduct is detrimental to Medicare. However, CMS cannot place a pharmacy on the Preclusion List because the pharmacy has billed Part D inappropriately. CMS should expand the reasons for which it may add a pharmacy to the Preclusion List to include inappropriately billing Part D or other Part D-related conduct that CMS determines is detrimental to the program. This would provide protections for Part D and other parts of the Medicare program.

- **Apply the Preclusion List payment prohibitions to pharmacies and other providers that dispense Part D drugs**

  The Preclusion List includes pharmacies with conduct that is detrimental to the program. To better protect the Part D program from fraud, waste, and abuse, CMS should prohibit all Part D sponsors from paying precluded pharmacies and other providers that dispense Part D drugs.

  Under the current rules, Part D sponsors are not prohibited from paying precluded pharmacies and other providers. Instead, CMS expects—but does not require—sponsors to remove precluded pharmacies from their networks. Without a requirement that prevents payment, precluded pharmacies can continue to bill and be paid by Part D even after these pharmacies are proven to be detrimental to the program.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with all three of our new recommendations.

With regard to the first recommendation—to allow revocation of Medicare enrollment for inappropriate billing of Part D—CMS concurred and stated that it will explore the feasibility of allowing revocation for this reason.

With regard to the second recommendation—to include on the Preclusion List pharmacies that inappropriately bill Part D—CMS concurred and stated that it will explore the feasibility of including these pharmacies on the Preclusion List. CMS noted that currently, only provider types that are eligible to enroll in Medicare can be placed on the Preclusion List.

With regard to the third recommendation—to apply the Preclusion List payment prohibitions to pharmacies and other providers that dispense Part D drugs—CMS concurred and stated that, effective April 1, 2019, Medicare Advantage plans are required to deny payment for an item or service furnished by a pharmacy on the Preclusion List. CMS stated that it will explore the feasibility of prohibiting Part D sponsors from paying for Part D drugs dispensed by a pharmacy on the Preclusion List.

OIG appreciates CMS's program integrity efforts to protect Part D and urges CMS not only to determine the feasibility of our recommendations, but also to take appropriate action to implement them. In addition, we reiterate that OIG views enrollment—with its screening process—as an extremely effective way to protect the Medicare program, including Part D, and that OIG continues to recommend that CMS require all Part C and Part D providers and pharmacies to enroll in Medicare.

For the full text of CMS's response, see the Appendix.

METHODOLOGY

We based this issue brief primarily on three key data sources: a document review of CMS's policies; an analysis of prescription drug event (PDE) records and records from the Provider Enrollment, Chain and Ownership System (PECOS); and structured interviews with CMS staff.

Document Review

We reviewed documentation—including regulations and guidance—about CMS policies relevant to enrollment, revocation, and the Preclusion List.

Analysis of PDE Records and PECOS Data

We analyzed PDE records and PECOS data to determine the extent to which pharmacies that billed Part D were enrolled in Medicare in 2017. PDE records contain information about the drugs that each pharmacy bills to Part D. PECOS records contain information about providers enrolled in Medicare.

We based our review on all PDE records for 2017. A Part D sponsor submits a PDE record to CMS each time a drug is dispensed to a beneficiary enrolled in its plan. Each PDE record contains information about the drug and beneficiary, as well as the identification numbers for the pharmacy and the prescriber. Using PDE records, we identified all National Provider Identifiers (NPIs) that billed for Part D drugs. To ensure that all of these NPIs were pharmacies, we compared these NPIs to the National Council of Prescription Drug Programs (NCPDP) database, the National Plan and Provider Enumeration System (NPPES), and PECOS. We included all types of pharmacies, such as retail pharmacies, long-term-care pharmacies, and mail-order pharmacies. In total, we identified 69,922 pharmacies.[20] Next, we matched these pharmacies' NPIs with PECOS records to identify the number and the proportion of Part D pharmacies that were enrolled in Medicare in 2017.[21]

We then determined whether pharmacies with certain characteristics were less likely to be enrolled. We calculated the proportion of pharmacies that were independently owned (vs. chain pharmacies). We also determined whether pharmacies identified as being high-risk were less likely to be enrolled. We used the High-Risk Pharmacy Assessment Tool reports to identify pharmacies that were high-risk in 2017.[22] CMS develops these reports to identify high-risk retail pharmacies that have aberrant Part D billing patterns.

Next, we determined the number of Part D pharmacies that had their Medicare enrollment revoked at any point in 2017. To do this, we identified pharmacies in the PECOS data that had an enrollment status of "revoked." We then identified the number of pharmacies that billed Part D for drugs after their enrollments had been revoked. To do this, we compared the dates of revocation to the dates of service on the pharmacies' PDE records. For these pharmacies, we calculated the total amount

that Part D paid them for drugs dispensed in 2017 after their enrollments had been revoked.[23]

Structured Interviews With CMS Staff

We conducted structured interviews with CMS staff to gain a better understanding of enrollment, revocation, and the Preclusion List. Our questions focused on the enrollment process, the reasons CMS may revoke a pharmacy's enrollment, and how revocation applies to Part D. We also asked about how the Preclusion List applies to pharmacies.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX: AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: January 31, 2020

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Issue Brief: Key Medicare Tools to Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D (OEI-02-15-00440)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to conducting robust program integrity efforts in Medicare Part D.

Because pharmacies billing for Part D drugs contract with sponsors, submit claims to sponsors, and do not directly bill Medicare, they are not required to enroll in Medicare. CMS expects Part D sponsors to exercise oversight over their network pharmacies, as they have the claims data necessary to review for and detect aberrant billing patterns. To assist Part D sponsors in their oversight, CMS utilizes two contractors: the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) and the Investigations MEDIC (I-MEDIC). CMS uses the I-MEDIC to identify and investigate potential fraud, waste, and abuse in Medicare Part C and Part D, and to refer cases to law enforcement agencies when necessary. CMS has directed the NBI MEDIC to produce quarterly reports on high-risk pharmacies, which CMS shares with Part D sponsors as a resource for their own internal program integrity activities.

Additionally, Part D sponsors report potential fraud to the NBI MEDIC through a system that allows CMS, the NBI MEDIC, and plan sponsors to more easily share information and help combat potential fraud, waste, and abuse in the Medicare Part C and Part D programs. CMS's federal law enforcement partners can also access this data.

More recently, CMS has established a preclusion list in Medicare Parts C and D of individuals and entities that are revoked from Medicare, are under an active reenrollment bar, and the underlying conduct that led to the revocation is determined to be detrimental to the best interests of the Medicare program, or who have engaged in behavior for which CMS could have revoked the individual or entity had they been enrolled in Medicare and the underlying conduct that would have led to the revocation is determined to be detrimental to the best interest of the Medicare program. Effective April 1, 2019, Part D plans must reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List. The intent of the preclusion list is to safeguard beneficiaries and the Medicare program from abusive prescribers in instances where beneficiaries seek services from prescribers who have chosen not to enroll in Medicare.

CMS expects Part D sponsors to remove precluded pharmacies from their networks. Also effective April 1, 2019, Medicare Advantage plans are required to deny payment for an item or service furnished by a pharmacy on the Preclusion List.

CMS believes that focusing on preventing Medicare Part D coverage of prescriptions written by prescribers who pose an elevated risk to Medicare beneficiaries through the Preclusion List and other methods is the most effective means of protecting beneficiaries as well as safeguarding the Medicare trust funds.

CMS takes seriously its responsibility to oversee program integrity in Medicare Part D, as exemplified by the many efforts currently underway, and appreciates the OIG's additional review into this area. OIG's recommendations and CMS's responses are below.

OIG Recommendation
CMS should allow revocation of Medicare enrollment for inappropriate billing of Part D.

CMS Response
CMS concurs with this recommendation. Currently, pharmacies can enroll in Medicare Part B as mass immunizers or DME suppliers. CMS will explore the feasibility of allowing revocation of Medicare enrollment for inappropriate billing of Part D.

OIG Recommendation
CMS should include on the Preclusion List pharmacies that inappropriately bill Part D.

CMS Response
CMS concurs with this recommendation. CMS will explore the feasibility of including pharmacies that inappropriately bill Part D on the Preclusion List. Currently, only provider types that are eligible to enroll in Medicare can be placed on the preclusion list.

OIG Recommendation
CMS should apply the Preclusion List payment prohibitions to pharmacies and other providers that dispense Part D drugs.

CMS Response
CMS concurs with this recommendation. Effective April 1, 2019, Medicare Advantage plans are required to deny payment for an item or service furnished by a pharmacy on the Preclusion List. CMS will explore the feasibility of prohibiting Part D sponsors from paying pharmacies on the Preclusion List.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

ACKNOWLEDGMENTS

Miriam Anderson served as the team leader for this study. Other Office of Evaluation and Inspections staff from the New York regional office who conducted the study include Margaret Himmelright and Jason Kwong. Office of Evaluation and Inspections staff who provided support include Adam Freeman and Christine Moritz.

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Nancy Harrison and Meridith Seife, Deputy Regional Inspectors General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

ENDNOTES

[1] Prior to November 2019, the re-enrollment bar was 1 to 3 years. It was extended to 10 years in November 2019.

[2] CMS may also preclude providers from prescribing Part D drugs; however, it may not preclude pharmacies from dispensing Part D drugs.

[3] This represents the price paid to the pharmacy at the point of sale. It includes the amount paid by Part D sponsors; by the Government; and by, or on behalf of, beneficiaries. It is not adjusted for rebates; coverage gap discounts; or other direct or indirect remuneration.

[4] CMS relies on Part D sponsors to oversee pharmacies that enroll in their networks.

[5] CMS has a separate enrollment process for pharmacies that bill for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and pharmacies that bill for Part B drugs, such as oral cancer drugs, immunosuppressant drugs, and the influenza vaccine. For more information about the enrollment process, see CMS, *Medicare Program Integrity Manual*, ch. 15, "Medicare Enrollment," 15.4.2.4, February 2, 2019. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c15.pdf on June 5, 2019. For more information about Part B coverage, see CMS, *Medicare Benefit Policy Manual*, ch. 15, "Covered Medical and Other Health Services," July 12, 2019. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf on September 20, 2019.

[6] 42 CFR § 423.505(b)(18). In addition, Medicare Part D covers drugs from out-of-network pharmacies under certain circumstances. In these cases, the beneficiary, rather than the pharmacy, typically submits these claims to the sponsor for reimbursement. For more information about network and out-of-network pharmacies, see CMS, *Medicare Prescription Drug Manual*, ch. 5, "Benefits and Beneficiary Protections," September 2011, sections 10.2, 50, and 60.

[7] In total, CMS identified 563 pharmacies as "high risk" in its Quarterly High-Risk Pharmacy Report for 2017. Of these 563 high-risk pharmacies, 234 are not enrolled.

[8] In total, 14,314 of the 64,812 retail pharmacies are not enrolled.

[9] 42 CFR § 424.535. In some cases, CMS may revoke a pharmacy's enrollment only with regard to certain parts of the Medicare program. For example, CMS may revoke a pharmacy's enrollment so that it may not bill for DMEPOS or for Part B drugs.

[10] Depending on the reason a pharmacy's enrollment is revoked, it may be prohibited from re-enrolling in Medicare for 1 to 10 years. If the pharmacy's enrollment is revoked for a second time, CMS may impose a reenrollment bar of up to 20 years. See 42 CFR § 424.535(c).

[11] See 42 CFR § 424.535(a).

[12] Part C plans are prohibited from paying pharmacies that are on the Preclusion List. Part C plans are not prohibited from paying pharmacies that are revoked but are not included on the Preclusion List.

[13] Part D plans are allowed to pay for Part D covered drugs dispensed by precluded pharmacies. Part D plans are not allowed to pay for drugs prescribed by precluded prescribers. 42 CFR § 423.120(c)(6), 84 Fed. Reg. 15680, 15791 (Apr. 16, 2019).

[14] See CMS, memorandum (addressed to all Medicare Advantage organizations, Part D plan sponsors, 1876 cost plans, and Programs of All-Inclusive Care for the Elderly (PACE)), *Preclusion List Requirements*, November 2, 2018. Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/Sample_Beneficiary_Letter.pdf on June 5, 2019.

[15] 42 CFR §§ 422.2 and 422.222.

[16] CMS can place a pharmacy that is not enrolled on the Preclusion List if it has engaged in behavior for which CMS could have revoked Medicare enrollment (if the pharmacy had been enrolled in Medicare) and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the Medicare program. For example, CMS can revoke a pharmacy's enrollment if its owner is convicted of a felony offense that CMS determines to be detrimental to the Medicare program and its beneficiaries. If a similar situation occurs with a pharmacy that is not enrolled, CMS can add that pharmacy to the Preclusion List.

[17] The SUPPORT for Patients and Communities Act requires Part D sponsors to report any payment suspension imposed on a pharmacy pending investigation of credible allegations of fraud as of January 2020. See P.L. No. 115-271 § 2008.

[18] Notably, in April 2019, OIG participated in the largest ever law enforcement operation targeting prescription opioids, an operation that resulted in charges against several pharmacists. See Department of Justice, *Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals* (April 2019). Accessed at https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against on August 2, 2019. In addition, OIG reviews have revealed that certain pharmacies have questionable billing for opioids and other drugs. See OIG, *Questionable Billing for Compounded Topical Drugs in Medicare Part D*, OEI-02-16-00440, August 2018; OIG, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, OEI-02-15-00190, June 2015; and OIG, *Ensuring the Integrity of Medicare Part D,* OEI-03-15-00180, June 2015. For examples of additional OIG reviews on opioids in Part D, see OIG, *Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased*, OEI-02-19-00390, July 2019; OIG, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing,* OEI-02-17-00250, July 2017; and OIG, *Opioid Use in Medicare Part D Remains Concerning*, OEI-02-18-00220.

[19] See OIG, *The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness*, OEI-03-17-00310, July 2018.

[20] We did not include other types of entities, such as community health centers and clinics, that dispense drugs or health care practitioners who provide Part D-covered drugs and vaccines. In total, we excluded 23,238 entities that billed Part D that were not pharmacies. Together, these entities billed for less than 1 percent of all Part D drugs.

[21] We included all pharmacies with an "active" enrollment status at any point in 2017.

[22] This analysis is based on CMS's Quarterly High-Risk Pharmacy Report, released in March 2018, which analyzed pharmacy billing from January 1, 2017 to December 31, 2017. CMS shares these reports with Part D sponsors as an educational tool.

[23] To calculate total Part D billing, we summed four fields on each PDE record: ingredient cost, dispensing fee, sales tax, and vaccine administration fee. Together these fields represent the amount that the pharmacy was paid for the drug. It includes amounts paid by the Government; by the sponsor; and by, or on behalf of, the beneficiary.