

Comment Deadline Approaches for CMS's Proposed Changes to Medicare Advantage and Part D Programs for CY 2019:
Part 3: Part D Drug Management Programs Following Adoption of the Comprehensive Addiction and Recovery Act

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On November 28, 2017, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule titled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" ("Proposed Rule").¹ This Client Alert serves as the third and final installment of our three-part series on the Proposed Rule. [Part 1](#) of this series focused on negotiated prices for drugs,² and [Part 2](#) focused on beneficiary cost, access, and protection.³

This **Part 3** focuses on those sections of the Proposed Rule in which CMS sets out regulations implementing the Comprehensive Addiction and Recovery Act of 2016 ("CARA").⁴ Specifically, CARA includes new authority for the establishment of Medicare Part D drug management programs, which are to be effective on or after January 1, 2019.

Public comments on the Proposed Rule must be submitted to CMS no later than **5 p.m. EST on Tuesday, January 16, 2018.**

Drug Management Program for At-Risk Beneficiaries

CMS proposes a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse. Under such programs, sponsors could limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs." For plan

¹ 82 Fed. Reg. 56336 (Nov. 28, 2017) *available at* <https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>.

² Part 1 of this Client Alert is available at <https://www.ebglaw.com/CY2019-1>.

³ Part 2 of this Client Alert is available at <https://www.ebglaw.com/CY2019-2>.

⁴ Pub. L. 114-198 (July 22, 2016).

year 2019, CMS would designate all opioids as frequently abused drugs, except buprenorphine for medication-assisted treatment (“MAT”) and injectables.

Part D sponsors implementing a drug management program could limit an at-risk beneficiary’s access to coverage of opioids beginning on or after January 1, 2019, through a point-of-sale (“POS”) claim edit and/or by requiring the beneficiary to obtain opioids from one or more selected pharmacies and/or prescribers after case management and notice to the beneficiary. To do so, the beneficiary would have to meet clinical guidelines that factor in that he or she is taking a high-risk dose of opioids over a sustained time period and that he or she is obtaining them from multiple prescribers and multiple pharmacies.

1. Identification of “At-Risk Beneficiaries”

CMS proposes that a “potential at-risk beneficiary” and an “at-risk beneficiary” would be a Part D eligible individual who is identified using clinical guidelines to be at risk for misuse or abuse of frequently abused drugs or who has been identified by the prescription drug plan (“PDP”) in which the beneficiary was most recently enrolled as “potentially at-risk” or “at-risk.” Further, an “at-risk beneficiary” does not include beneficiaries who meet one of the exemptions from the at-risk designation, including beneficiaries who have elected to receive hospice care, are residents of long-term care facilities, or have a cancer diagnosis.

For plan year 2019, CMS would use the Overutilization Monitoring System (“OMS”) criteria established for plan year 2018 as the clinical guidelines for identifying at-risk beneficiaries for the Part D drug management program. Further, under these clinical guidelines, CMS proposes that prescribers associated with the same single Tax Identification Number (“TIN”) are counted as a single prescriber (unless any of the prescribers are associated with multiple TINs) and pharmacies with multiple locations that share real-time electronic data are treated as one pharmacy under the clinical guidelines.

2. Proposed Requirements of Drug Management Programs

CMS proposes the following requirements that a Part D plan sponsor must meet to operate a drug management program:

- **Written policies and procedures:** A sponsor must document its drug management program in written policies and procedures that are approved by the applicable Pharmacy and Therapeutics committee and reviewed and updated, as appropriate.
- **Case management/clinical contact/prescriber verification:** The sponsor’s clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary.

- ***Limitations on Access to Coverage for Frequently Abused Drugs:*** A sponsor may implement a POS claim edit for frequently abused drugs that is specific to an at-risk beneficiary or limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers, dispensed to the beneficiary by one or more network pharmacies, or both.
- ***Requirements for Limiting Access to Coverage for Frequently Abused Drugs:*** A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs unless the sponsor has (i) conducted the required case management and updated it; (ii) if necessary, obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate; and (iii) provided the required notices to the beneficiary.
- ***Beneficiary Notices:*** A sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs must provide an initial written notice to the beneficiary. The initial notice must indicate the sponsor's intent to limit the beneficiary's access to frequently abused drugs. The sponsor would then provide a second notice to an at-risk beneficiary when it actually limits the beneficiary's access to coverage for frequently abused drugs (including the effective and end date of the limitation). Alternatively, the sponsor would provide an alternate second notice if it decides not to limit the beneficiary's access to coverage for frequently abused drugs. A Part D sponsor must provide the second notice or the alternate second notice, as applicable, on a date that is not less than 30 days and not more than the earlier of the date that the sponsor makes the relevant determination or 90 days after the date of the initial notice.
- ***Provisions Specific to Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers:*** A Part D sponsor must not limit an at-risk beneficiary's access to coverage for frequently abused drugs unless at least six months have passed from the date that the beneficiary was first identified as a potential at-risk beneficiary and the beneficiary meets the clinical guidelines to be determined an at-risk beneficiary. If a beneficiary submits preferences for prescribers and/or pharmacies from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must take such preferences into account (unless the sponsor determines that the selection or change of a prescriber or pharmacy would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary). The sponsor must notify the prescriber and/or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and/or pharmacy is being selected as the beneficiary's designated prescriber and/or pharmacy for frequently abused drugs.
- ***Drug Management Program Appeals:*** The identification of an individual as an at-risk beneficiary for prescription drug abuse under a Part D drug management program, a coverage determination made under such a program, the selection of a prescriber or pharmacy, beneficiary-specific POS claim edits, and information sharing for subsequent plan enrollments are "at-risk determinations" that are

subject to reconsideration and appeal. CMS proposes that at-risk determinations will be adjudicated under the existing Part D benefit appeals process.

- **Termination of a Beneficiary's Potential At-Risk or At-Risk Status:** The identification of an at-risk beneficiary as such will terminate when the beneficiary demonstrates that he or she is no longer likely to be an at-risk beneficiary, or at the end of a 12-calendar month period calculated from the effective date of the limitation, as specified in the second notice provided by the sponsor.
- **Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments:** CMS will identify each potential at-risk beneficiary to the sponsor of the PDP in which the beneficiary is enrolled. A sponsor that operates a drug management program must disclose any data and information to CMS and other Part D sponsors that the agency deems necessary to oversee Part D drug management programs at a time, and in a form and manner, specified by CMS.

Special Enrollment Period Limitations for At-Risk Dually-Eligible or Low-Income Subsidy-Eligible Beneficiaries

CMS proposes to limit the use of the special enrollment period (“SEP”) for dually- or other low income subsidy (“LIS”)-eligible beneficiaries (the “duals’ SEP”) who are identified as at-risk or potentially at-risk for prescription drug abuse under a Part D plan sponsor’s drug management program.

The duals’ SEP currently allows dually-eligible and LIS-eligible beneficiaries to enroll in, disenroll from, or change Part D plans throughout the year, unlike other Part D enrollees who generally may make enrollment changes only during the annual election period. CMS proposes that, once an individual is identified as a potential at-risk beneficiary and the sponsor intends to limit the beneficiary’s access to coverage for frequently abused drugs, the beneficiary would be unable to use the duals’ SEP to enroll in a different plan or disenroll from the current Part D plan. If the Part D plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 90 days from the initial notice, the “potentially at-risk” designation and the duals’ SEP limitation would expire. If the sponsor determines that the potential at-risk beneficiary is an at-risk beneficiary, the duals’ SEP would not be available to that beneficiary until the date that the beneficiary’s at-risk status is terminated or at the end of the applicable 12-month period, whichever is sooner.

Part D Opioid Drug Utilization Review Policy and Overutilization Monitoring System

CMS proposes to codify the current Part D Opioid Drug Utilization Review (“DUR”) policy and OMS⁵ by integrating this current policy with the proposals for implementing the drug management program provisions described above. Under the current policy, CMS expects Part D PDPs to engage in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from

⁵ See CMS, “Improving Drug Utilization Review Controls in Part D”, available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>.

multiple prescribers and multiple pharmacies that may not know about each other. Once such enrollees are identified through retrospective prescription drug claims review, Part D plan sponsors are expected to diligently assess each case and, if warranted, have their clinical staff conduct case management with the beneficiary's opioid prescribers until the case is resolved.

Next Steps

Plan sponsors, manufacturers, pharmacies, and other key stakeholders should consider the potential implications of the Proposed Rule with respect to benefits, as well as the products offered under such benefits, including the potential impact of these proposed programs on their business plans, operations, systems, policies, and financial projections/budgeting. Stakeholders should consider submitting comments to CMS on these proposed program provisions, especially with respect to areas in the Proposed Rule on which CMS specifically seeks comment, including the following:

- CMS's intention to codify the current DUR policy, and whether the Proposed Rule fails to codify any features of this policy;
- the proposed approach for identifying frequently abused drugs, and whether sponsors should be allowed to continue to implement beneficiary-specific claim edits, as under the current DUR policy, for non-opioid medications (such as benzodiazepines);
- the proposal to require a six-month waiting period before limiting an at-risk beneficiary's access to coverage of frequently abused drugs to one or more selected prescribers, and whether this waiting period would reduce provider burden; and
- whether additional categories of beneficiaries should be exempt from the Part D drug management program, including beneficiaries receiving palliative and end-of-life care, beneficiaries in other health care facilities where medication is supervised, and beneficiaries with debilitating disorders or receiving MAT for substance abuse disorders.

Epstein Becker Green is available to assist with drafting and submitting comments to the Proposed Rule and to provide a more detailed understanding of the Proposed Rule's implications and the manner in which particular requirements may be implemented effectively.

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*This Client Alert was authored by **Constance A. Wilkinson**, **Helaine I. Fingold**, and **Lesley R. Yeung**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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