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## CMS Proposes Major Rule Changes to Increase Payment Accuracy and Improve Program Integrity in Medicare Part C and Part D



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**O**n Jan. 10, the Centers for Medicare & Medicaid Services published proposed *rules* labeled as “policy and technical” changes to the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) Programs. Comments on the proposed rules are due March 7.

If adopted as drafted, these rules will not only impact how Medicare Advantage Organizations (MAO) and Part D Prescription Drug Plan (PDP) sponsors operate and interact with their contractors, beneficiaries, and the government, but will also impact the operations of all health care entities involved in providing drug prod-

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ucts under Part C and Part D, including pharmacy benefit managers (PBMs), pharmacies, physicians, and pharmaceutical manufacturers.

### Proposed Rule Provisions Impact Plan Operations

CMS states that the purpose of many of the proposed regulations is to improve payment accuracy and correct perceived program integrity issues in Medicare Part C and Part D. MAOs and PDP sponsors should carefully consider how the proposals may impact their plan operations.

Additionally, plans and providers should recognize that through the “data driven” strategy underlying the rule changes, CMS will increase access to information and data about Part C and Part D reimbursements for the government, government contractors, other health care providers, and the public. This will create even greater data reporting and disclosure requirements for MAOs and PDPs.

### Establishing Liability for Overpayments

The proposed regulations implement the Affordable Care Act requirement that MAOs and PDP sponsors report and return identified overpayments within sixty (60) days and that the failure to do so is potentially actionable under the Federal False Claims Act. MAOs and PDP sponsors would be required to report and return any identified overpayments for the six most recent completed payment years. This six-year term corresponds to the six-year statute of limitations for actions brought under the Federal False Claims Act.

The 60-day repayment requirement for Medicare providers has existed in regulation for some time, but enforcement has been complicated by the government's failure to clearly define what constitutes an "identified overpayment."

In the proposed rules, CMS broadly defines an "overpayment" in Part C and Part D as any funds received or retained to which a plan, after applicable reconciliation, is not entitled; an "identified overpayment" exists if the plan has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. The plan must exercise reasonable diligence to determine the accuracy of information it receives and whether an overpayment may exist.

However, CMS does **not** say that the amount of an overpayment must be quantified before it is considered identified. Yet how can a plan realistically report and return an overpayment if the amount of the overpayment is not yet quantified?

The regulations would also require the chief executive officer, chief financial officer, or chief operating officer of an MAO or PDP sponsor to certify that any information provided to the government regarding an overpayment is accurate, complete, and truthful.

## Prohibiting Co-Payment and Premium Waivers

The proposed rules codify CMS's prohibition on PDP sponsors waiving or discounting the collection of beneficiary premiums or co-payments. According to CMS, the failure of a sponsor to collect cost-sharing after the fact is a violation of the existing uniform benefit regulation.

While on its face, the prohibition will not apply to waivers/discounts offered by pharmacies, CMS is adding new language stating the prohibition is intended to apply if the waiver/discount is offered directly by the PDP sponsor, or "indirectly through related entities" such as a related party pharmacy.

For the purposes of this rule, pharmacies are considered to be related to a PDP sponsor if they (i) have common ownership and control, (ii) perform some of the PDP sponsor's management functions under contract or delegation, (iii) furnish services to Medicare enrollees under an oral or written agreement, or (iv) lease real property to sell materials to the PDP sponsor at a cost of more than \$2,500 during a contract period.

If enacted, the language of the new rule puts the onus on the PDP sponsors to ensure related-party pharmacies are not routinely waiving co-payments. The proposed rules also require PDP sponsors to refund any "amounts incorrectly collected" for premiums or cost sharing from beneficiaries under the time frames applicable to other overpayment recoveries.

The term "amounts incorrectly collected" is defined as an amount that exceeds the monthly beneficiary Part D premium limits or exceeds permissible cost-sharing amounts.

## Establishing Direct Access to Part C and Part D Contractor Records

The proposed rules enhance CMS's existing audit, evaluation, and inspection authority by authorizing CMS and its designees (such as audit contractors) to di-

rectly request and collect Part C and Part D records from an MAO or PDP sponsor's first tier, downstream, or related entities, including PBMs, pharmacies, and other entities that contract to administer Medicare prescription drug benefits.

Presently, the government and its contractors have no authority to request or collect records on Part C or Part D services directly from entities other than the MAO or PDP sponsor.

Given that PBMs and pharmacies generally contract with the MAOs and PDP sponsors, not directly with the government, the regulation does not specify how the government intends to enforce this new regulatory provision. It may be that the government will require the MAOs and PDP sponsors to take action against uncooperative contracting entities.

## Requiring Plans to Hire Independent Auditors and Establishing RAC Appeals

CMS proposes to require that MAO and Part D sponsors hire independent auditors to perform full audits, partial audits, or validation audits to determine compliance with CMS requirements. Due to resource limitations, CMS states that it is "constrained" in its auditing functions and seeks to transfer those responsibilities to outside auditors who will conduct the audits under instructions and guidance from CMS, and will report the findings to CMS. Presumably, although not stated in the proposals, plans will be responsible for the costs of these audits.

Significantly, this section of the proposed rules does not address the role of ZPIC and RAC auditors already charged with audit responsibility under Part C and Part D. It also does not address how the costs for independent auditors will be viewed for Medical Loss Ratio purposes.

In a separate section of the proposed rules, CMS commends the RAC process and adopts a RAC Appeals process for Part C and Part D RAC overpayment determinations, which includes a hearing before an Administrative Law Judge. Absent from the commentary is any reference to the fact that Medicare provider appeals are currently facing a two-year moratorium on assignment to an Administrative Law Judge due to a crushing caseload of RAC-related appeals. Thus, CMS is seeking to institutionalize an appeals process that is not working.

## Expanding Release of Medicare Part D Data

CMS believes that current regulations limiting the release of prescription drug event (PDE) data are outdated and through the proposed rules seeks to expand the release of PDE data, including unencrypted prescriber, pharmacy, and plan identifiers.

The new rules would allow the release of Medicare Part D data for program integrity purposes, such as coordination with Medicaid, but the latter provision is broadly drafted, and release of records for program integrity purposes is not restricted to government or public entities—the reference to Medicaid is only an example.

CMS believes that it can broaden the release of PDE data while protecting beneficiary confidentiality and the commercially sensitive data of PDP sponsors. CMS

is also seeking comments on whether the current restriction on release of PDE data for commercial purposes should remain in effect.

The proposed rules represent another step in the government's shift towards transparency and accessibility of Medicare records. These rules should be viewed in conjunction with the recent CMS announcement that it will consider disclosing physician Medicare payment information upon request and will also make aggregate data regarding Medicare payments for physician services publicly available. Having more Medicare data publicly available will have unintended consequences, as more that data will be also be available to marketers, journalists, whistleblowers, and others.

## **Establishing New Reporting Requirement for EGWPs**

In 2012, CMS published guidance regarding application of the Medicare Coverage Gap Discount to Employer Group Waiver Plans (EGWPs). Through that guidance, CMS announced that benefits offered by EGWPs to their beneficiaries in the Coverage Gap were non-Medicare Other Health Insurance (OHI) and that the discount offered by manufacturers in the Coverage Gap should be applied before the application of any OHI.

In the proposed rules, CMS attempts to further clarify their guidance and states that the discounts will be based upon the Part D Defined Standard benefits for all EGWPs beginning in 2014.

In commentary accompanying the proposed rules, CMS expresses concern that it is unable to determine whether the discount offered through the Coverage Gap Discount Program will always be used to offset an EGWP beneficiary's final out-of-pocket cost sharing but recognizes that it does not have authority to require any specific application of the Coverage Gap Discount payments to OHI benefits since they are, by definition, non-Medicare private benefits.

Thus, to address its concern, CMS would require EGWPs to disclose to each employer group client, in a uniform fashion, the projected and actual Discount Program payments attributable to that client's enrollees. EGWPs will need to consider what steps will be necessary in order to operationalize such reporting.

## **Scrutinizing Part D Prescribers**

In response to criticism that it has failed to monitor excessive prescribing activity in Part D, CMS seeks to impose new limitations on who may prescribe the drugs that will be covered by Part D.

CMS intends to require that by January 2015, all PDP sponsors and PBMs have procedures in place to ensure they are denying pharmacy claims for Part D drugs when the physician or eligible provider who prescribed the drug is not an approved Medicare provider.

Under the new rules, drugs prescribed by non-enrolled providers will only be covered if the prescribing provider follows established opt-out procedures, which include filing an affidavit listing their NPI with a Medicare Administrative Contractor. CMS also is seeking authority to deny Medicare enrollment to a practitioner whose DEA certificate is suspended or revoked or who is under a state licensing restriction.

The proposed rules will therefore exclude Part D coverage for prescriptions written by licensed health care providers who choose not to enroll in Medicare, obtain an NPI, or follow the opt-out process, including prescriptions written by practitioners, such as dentists, who have never had to enroll in Medicare. It also will require plans and downstream entities to regularly update screening practices for prescribing providers.

CMS proposes broad new authority to revoke a provider's Medicare enrollment under certain circumstances, including a pattern of abusive or excessive prescribing, or as a result of adverse malpractice or administrative actions. Because Medicare coverage for drugs is, under the new rules, dependent on the enrollment status of the prescriber, CMS theorizes that revoking a rogue prescriber's Medicare enrollment will result in non-coverage of that practitioner's prescribed drugs.

The criteria for CMS revocation are broadly drafted and may be a source of concern to health care practitioners who treat and prescribe drugs for chronically ill Medicare beneficiaries. What may be considered excessive narcotic prescribing for a relatively healthy 72 year old may not seem excessive to a 72 year old suffering from chronic back pain. Under the proposal, CMS and not the beneficiary or the physician would decide what is excessive.

## **Increasing Transparency in Drug Networks and Drug Pricing**

Provisions in the proposed rules will alter the structure and manner of how drugs actually reach beneficiaries. Aside from the fact that prescriptions for covered drugs must be written by Medicare enrolled or approved practitioners, the rules impose new requirements for "preferred cost sharing" networks, eliminating the use of preferred pharmacy networks.

Any willing pharmacy must be given the opportunity to participate in a preferred cost sharing network. The rules also impose new limits on mail-order cost sharing and new timetables for mail-order filling of prescriptions.

The new rules redefine what constitutes a negotiated price for a drug, in an attempt to mandate that all price concessions and fees be reflected in Part D reporting. The rules would require plan sponsors to disclose and update prescription drug standards used for reimbursement and to share those with pharmacies and with CMS.

The proposed rules also establish parameters for CMS to involve itself in contract negotiations between PDP sponsors and pharmacies, but only when an issue implicates CMS requirements, such as whether a willing pharmacy has been provided access to a preferred cost sharing network. CMS did state that it will not develop formulary guidelines that favor a particular manufacturer's product, and it will not favor a particular price reimbursement methodology over any other methodology.

## **Establishing Additional Program Integrity/Payment Accuracy Provisions**

The proposed rules contain a myriad of other provisions intended to promote program integrity and payment accuracy, including:

- Establishing citizenship and legal presence as eligibility requirements for beneficiary enrollment in Part C and Part D;
- Adopting specific changes impacting drug coverage for long-term care beneficiaries, including prohibiting arrangements that “penalize the offering and adoption of more efficient LTC dispensing techniques”;
- Allowing MAOs to offer reward and incentive programs to current enrollees under specified conditions;
- Prohibiting MAOs from developing and implementing their own training “or providing supplemental training materials” to fulfill the requirement that first tier, downstream, and related entities receive CMS training;
- Shortening the notice requirement for proposed Part C or Part D contract terminations from 90 days to 45 days;
- Expanding CMS’s authority to impose monetary sanctions or penalties for specified conduct such as nonconsensual beneficiary enrollment or transfer, or marketing violations; and
- Requiring PDP sponsor P&T Committees to have established procedures to address disclosed financial interests which may present a conflict of interest.

## Proposed Rules Change the RADV Process

The Medicare Advantage Risk Adjustment Data Validation (RADV) system is complicated. Both MAOs and CMS conduct reviews of data at various points during each plan year to determine whether the information that is used to calculate payments to MAOs is accurate. The proposed rules signal that CMS proposes to change the process again.

### Conducting Medical Record Reviews

The rules would require that MAOs “look both ways” when conducting medical record reviews. Specifically, under the proposed rule, MAOs must design medical record reviews to identify errors in diagnoses submitted to CMS, regardless of whether the errors will result in the MAO receiving additional payments or having to pay money back to CMS.

This proposed requirement comes as no surprise since the few cases that have been brought in this area often cite MAOs for only reviewing medical records in order to potentially increase the payments they may receive.

### Submitting Risk Adjustment Data

CMS proposes to prohibit the late submission of risk adjustment data except for purposes of correcting an overpayment and proposes to announce the submission deadline, rather than establishing it as January 31 of each year (the current deadline).

### Conducting a RADV Audit

Currently, only CMS may conduct RADV audits, but under the proposed rules, the secretary of the Depart-

ment of Health and Human Services may also conduct RADV audits. This is a departure from current practices and would invite other sub-agencies, such as the HHS Office of Inspector General (OIG) into the field of RADV. The OIG previously conducted audits relating to MA risk adjustment, but no entity, other than CMS, has been tasked with conducting RADV audits or recouping funds based on such audits.

## Appealing RADV Findings

The proposed rules would change the RADV appeal processes. Currently, MAOs appealing RADV findings have two separate appeal tracks, one that addresses medical record review determinations (two steps) and a separate process for appeals relating to the RADV payment error calculation (three steps).

The proposed rules would combine the processes and MAOs could request to appeal their RADV audit findings one time and specify whether they want to appeal either their medical record review determination(s), payment error calculation, or both. Regardless of the issue appealed, the appeal process would include three steps: (i) reconsideration; (ii) hearing officer review; and (iii) CMS Administrator-levels of review.

During a RADV audit, an MAO may submit multiple medical records (up to five) to substantiate a diagnosis of a medical condition submitted by the MAO to CMS for risk adjustment purposes. This medical record requirement has been referred to as the “one best medical record” policy even though CMS allows more than one record.

Without explanation, the proposed rules delete the term “the one best medical record.” It appears that under the proposed rules, MAOs will continue to be able to submit multiple records to substantiate a diagnosis during a RADV audit but will be permitted to submit only one of those medical records for appeal purposes. The proposed rules also impose a new burden of proof on appeal requiring that an MAO demonstrate that, based on a preponderance of the evidence, CMS’s determination was erroneous.

## Conclusion

The publication of the proposed rules has already generated much controversy.

On Feb. 18, a coalition of more than 230 diverse health care providers, trade associations, charitable associations, and patient advocacy groups banded together to urge CMS to withdraw the rules, stating the rules will not only fail to achieve intended goals but “will reduce choice and impose higher costs on beneficiaries and taxpayers.”

On Feb. 19, three high ranking members of Congress also urged withdrawal, calling the rules “a bureaucratic overreach” that undermines the success of Part D, threatens drug coverage for millions of seniors, and adds unnecessary costs for taxpayers. CMS will have to carefully sift through all the submitted comments and make some hard choices on the feasibility of its proposals.

Timing is going to impose hardships. Given the comments and controversy so far, it is hard to imagine that CMS will finalize these rules before the winter of 2014. Yet many provisions were drafted to be effective in 2015, thereby denying plans and contractors adequate

time to design the necessary systems to implement all that the rules would require. Further, the impact of some of the rules may not be clear until they are actually in effect.

When a PBM or pharmacy must deny a beneficiary Part D coverage for a medically-necessary prescription written by his/her dentist because of the new rules, the controversy and criticism may be raised to new levels.