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CMS Proposes Major Changes to Medicare Parts C and D

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On January 10, the Centers for Medicare & Medicaid Services (CMS) published proposed rules labeled as "policy and technical" changes to the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) Programs. Comments to the proposed rules must be submitted by March 7, 2014.

If adopted as drafted, these rules will significantly impact how Medicare Advantage (MA) organizations and Part D Prescription Drug Plan (PDP) sponsors operate and interact with their contractors, beneficiaries, and the government. The proposed rules will also impact the operations of all health care entities involved in providing drug products under Parts C and D, including pharmacy benefit managers (PBMs), pharmacies, physicians, and pharmaceutical manufacturers.

Impacted parties and entities will want to carefully review the text of the proposed rules, along with CMS's justification for the rules, and consider submitting comments by the deadline. Mintz Levin is hosting a webinar on January 29, 2014 at 1:30 pm EST, to provide a forum for interested parties to discuss the proposed rules and potential comments.

Limiting Who Can Offer Medicare Plans and Plan Expansion

With the goal of providing beneficiaries with "more meaningful plan choices," CMS proposes significant changes to the conditions for MA and Part D plan participation.

Medicare Advantage Contracts

The proposed rules increase the consequences for Medicare Advantage Organizations (MAOs) that have their contracts terminated or elect not to renew their contracts with CMS. The rules also introduce changes that impact entities and related parties that offer or are considering offering a cost contract.

CMS proposes to expand its authority to deny any contract or service area expansion of an MAO that has not renewed its contract with CMS or has participated in a mutual contract termination within the last two years, regardless of contract type, product type, or service area. This represents a significant expansion of CMS's current authority, which only prohibits an MAO from not renewing or mutually terminating a contract and then seeking to offer either the *same* plan type (e.g., private-fee-for-service plan, HMO plan) in the *same* service area.

CMS is concerned that MAOs that have their contract terminated for low enrollment are able to apply for a new contract the following year for substantially the same plan that was terminated. To remedy this, CMS proposes to require MAOs to agree that if CMS terminates a contract with the MAO due to low plan enrollment, the MAO will not submit a new bid for a period of two years for the same type of plan (e.g., MA plan, MA SNP plan) in a region where CMS previously terminated the contract.

Currently, an MAO is prohibited from offering a cost contract in the same service area in which it offers an MA plan. This prohibition seeks to ensure that MAOs do not move higher risk enrollees from one plan to another in order to take advantage of the different Medicare payment rules for the two different plan types. CMS proposes to broaden this prohibition so that related entities (i.e., ones that share a parent organization) are prohibited from offering an MA plan and a cost contract in the same service area.

Medicare Part D Contracts

CMS proposes a wide range of material changes that limit both plan expansion and the creation of new plans under Medicare Part D.

CMS proposes to require an entity seeking to contract as a PDP sponsor, or an MAO offering Part D benefits, or its contracted first tier, downstream or related entities, to have either one full benefit year serving as a PDP sponsor, or at least one full benefit year of experience performing "key" Part D functions for another PDP sponsor. CMS considers the following areas to be "key" Part D functions: (i) authorization, adjudication, and processing of pharmacy claims at the point of sale; (ii) administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and (iii) operation of an enrollee appeals and grievance process. In addition, newly contracted PDP or MA-PD (Medicare Advantage-Prescription Drug Plan) plan sponsors would be required to meet a specified "essential operations test," which would initially test a plan sponsor's command of Part D benefit administration rules and systems and may become more sophisticated in the future to test plan sponsors' systems real-time using test data.

Under the proposed rule, applicants for stand-alone PDP contracts must have either actively provided health insurance or health benefits coverage (i.e., serving as a state-licensed, risk-bearing entity) for two continuous years immediately prior to submitting a contract application, or provided certain prescription drug benefit management services to a company providing health insurance or health benefits coverage for five continuous years immediately prior to submitting an application.

PDP sponsors' ability to expand operations would be significantly limited under the proposed rule. Parent organizations would be limited to one PDP sponsor contract per PDP region and stand-alone PDP sponsors would be limited to two bids per coverage year in each PDP region. CMS also intends to impose a two-year ban on any applications from PDP sponsors who, after announcement of low-income subsidy benchmarks, withdraw a bid prior to execution.

Throughout the proposed rule, CMS highlights the large number of organizations that participate in the Part D program either as plan sponsors (for 2014, 310 parent organizations own 578 legal entities offering 881 contracts) or as other organizations that perform key Part D functions on behalf of plan sponsors (over 300 for 2014). The proposed changes limiting both plan expansion and the creation of new plans are likely an effort by CMS to rein in the number of Part D plans offered as well as the number of new entities participating in the Part D program. In fact, CMS states that "it is in the Part D program's best interest to be more discriminating about the entities with which we partner to deliver the Part D benefit." Current PDP and MA-PD plan sponsors, as well as entities seeking to become new plan sponsors or contractors, should take note of CMS's significant proposals in this area.

Star Rating Terminations

MA and PDP sponsors receive plan ratings, or "star ratings," on a 1 star to 5 star scale. In addition to serving as an educational tool for beneficiaries, star ratings have become increasingly important in CMS's efforts to identify excellent and poor performing plans. Under the Affordable Care Act (ACA), MA plan sponsors may also receive quality bonus payments if their star ratings meet or exceed 4 stars. Two years ago, CMS promulgated a regulation giving CMS the authority to terminate Part C and Part D contracts when a plan sponsor failed to achieve at least a 3-star summary plan performance rating for three consecutive contract years. CMS noted that three years is enough time for plan sponsors to develop and implement a corrective action plan and for improved performance to be reflected in the star ratings issued during this three-year period.

MA-PD organizations receive a separate star rating score based on their Part C and Part D operations. The proposed rule grants CMS the authority to terminate an MA-PD contract if the contract receives below 3 stars in either its Part C or Part D ratings for three consecutive years. This proposal is consistent with the policy CMS

issued in the contract year 2014 Call Letter relating to the "low performing icon" that appears on the Medicare Plan Finder website and is assigned to contracts receiving less than 3 stars for their Part C or Part D summary ratings for the previous three consecutive years. In the 2014 Call Letter, CMS noted that it will assign the low performing icon to an MA-PD contract receiving 2.5 stars or lower for any combination of its Part C or Part D summary ratings for three consecutive years. CMS implemented this change due to concerns that an MA-PD contract may switch from poor performance in Part C to poor performance in Part D from year to year, yet continue to evade receiving the low performing icon.

Similar to the possible result that led to CMS's change in the 2014 Call Letter, MA-PD organizations could potentially alternate between a contract's Part C and Part D low star ratings (below 3 stars) from year to year under the current regulations. This creates the possibility that CMS would not have authority to terminate an MA-PD contract if, for example, the contract received low star ratings in Part C for two consecutive years, and in the next two years the Part C ratings improved but the Part D ratings became unsatisfactory. The proposal – one that CMS considers as closing a "loophole" – reiterates CMS's belief that if an MA-PD organization cannot achieve at least an "average" (3 star) rating across all of its Part C and Part D operations in at least one year out of three, it has failed to meet the requirements of a Medicare contractor and failed to take effective corrective action steps over a three-year period. The proposed change would be effective upon the release of the 2015 star ratings in September 2014.

Simplifying Agent/Broker Compensation and Relationships

CMS proposes to alter the way plans compensate independent agents and brokers. The current compensation structure for agents and brokers under Parts C and D uses a six-year cycle. Plans pay agents and brokers an initial rate for the first year, and a renewal rate paid in years 2 through 6 that equals fifty percent (50%) of the first-year compensation. On an annual basis, CMS publishes fair market value (FMV) compensation limits for these agent and broker payments.

CMS proposes to "simplify" the compensation structure and thereby limit possible incentives for agents and brokers to move enrollees for financial gain. Under the proposed rules, Part C and Part D plans may pay agents or brokers an initial amount for new enrollees that is no greater than the published FMV amount, and may pay up to thirty-five percent (35%) of the FMV amount for renewals in years 2 and beyond. These proposed changes would result in the renewal year payments changing each year if the plan sponsor chooses to pay thirty-five percent (35%) of the current FMV threshold. The current six-year cap on the agent/broker compensation cycle would also be removed.

Plan sponsors will want to pay close attention to the proposed changes relating to independent agent and broker compensation, as the rules are technical and require strict compliance. This area has been under regulatory scrutiny, as CMS has taken compliance actions against plan sponsors for failure to comply with compensation requirements. CMS's proposal simplifies the existing compensation structure, which may prove to alleviate some of the administrative burden of the current compensation rules.

CMS proposes a number of other changes to the agent/broker rules, including those described below.

First, CMS clarifies that agent/broker compensation rules are tied to a plan year (January 1 through December 31) and that payments to agent/brokers for a plan year may not cross calendar years or be paid based on an alternative annual cycle.

Second, CMS requires that payments to agents/brokers may not be made until January 1 of the compensation year and must be paid in full by December 31 of the compensation year. In other words, plan sponsors would have to wait until the beginning of the calendar year when a beneficiary's final annual enrollment period (AEP) enrollment becomes effective before paying the agent/broker for that compensation year.

Third, CMS clarifies that plan sponsors should recover compensation from the agent/broker only for the months that the beneficiary is not enrolled, unless the disenrollment took place within the first three months. CMS intends to provide further information in sub-regulatory guidance, but noted that in cases where disenrollment took place within the first three months and the disenrollment did not result (or could not have resulted) from an agent/broker's behavior, the plan sponsor would not be required to recover the compensation from the agent/broker.

Fourth, CMS limits the amount that can be paid as a referral fee to independent, captive, and employed agents and brokers to "a reasonable amount specified by CMS," which for 2014 has been set at $100. Referral fees paid to independent agents and brokers must be part of their total compensation, not to exceed the FMV for a particular calendar year.

Finally, CMS revises the agent and broker testing and training requirements to: (i) remove CMS endorsed or approved training and testing as an option; (ii) mandate that agents and brokers be trained annually on Medicare rules and regulations, and details specific to the plan products they intend to sell; and (iii) require agents and brokers to be tested annually to ensure appropriate knowledge and understanding of training topics.

Increasing Payment Accuracy and Program Integrity

The proposed rules contain a variety of regulatory changes related to improving payment accuracy and correcting perceived program integrity issues.

Liability for Overpayments

The proposed regulations implement the ACA requirement that MAOs and PDP sponsors must 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.

The proposed regulations define a number of terms that are key to implementing and enforcing the 60-day refund requirement. CMS broadly defines an "overpayment" as any funds received or retained to which the 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.

The proposed regulations also codify a six year look-back period. Under the rules, MAOs and PDP sponsors would be required to report and return any identified overpayments within the six most recent completed payment years. This six-year term correlates to the six-year statute of limitations for actions brought under the Federal False Claims Act.

In connection with these changes, the regulations 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.

Prohibition on Co-Payment and Premium Waivers

CMS intends to codify the existing prohibition on PDP sponsors waiving or discounting the collection of beneficiary premiums or co-payments. While the prohibition will not apply to waivers/discounts offered by pharmacies, it is intended to apply if the waiver/discount is offered through a PDP-related party pharmacy.

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. According to CMS, the fact that cost sharing is waived by a pharmacy related to a PDP sponsor may protect the pharmacy from sanction under anti-kickback laws, but it should not relieve the PDP sponsor itself from responsibility for violation of the uniform benefit provision.

The proposed regulations also requires PDP sponsors to refund any incorrect collection of premiums or cost sharing from beneficiaries under the time frames applicable to other overpayment recoveries.

Direct Access to First Tier, Downstream, and Related Entities

CMS proposes to enhance its existing audit, evaluation, and inspection authority by empowering CMS and its designees (such as audit contractors) to directly request and collect Part C and Part D records from an MAO or PDP sponsor's first tier, downstream, or related entities, which would include PBMs, pharmacies, and other entities

that contract with an MAO or PDP sponsor to administer Medicare prescription drug benefits. Presently, the government and its contractors have no right 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 MAO and PDP sponsors, not 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 MAO and PDP sponsors to take action against uncooperative contracting entities.

Additional Changes to Audit and Inspection Authority

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, plans will be responsible for the costs of these audits. Significantly, this section of the proposed rules and commentary 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.

Expanded Release of Medicare Part D Data

CMS believes that current regulations limiting the release of prescription drug event (PDE) data are outdated and seeks to greatly expand the release of PDE data, including unencrypted prescriber, pharmacy, and plan identifiers, to all types of requestors. CMS also seeks to clarify that the release of Medicare Part D data is authorized for program integrity purposes, such as coordination with Medicaid. However, it is important to note that the new provision is broad enough to authorize the release of data to private entities for program integrity purposes. CMS believes that it can broaden the release of PDE data while protecting beneficiary confidentiality and the commercially sensitive data of PDP sponsors. In light of the proposed changes, CMS is seeking comments as to whether the current restriction on release of PDE data for commercial purposes should remain in effect.

This regulatory proposal is another step in the government's shift towards transparency and accessibility of Medicare records. These transparency requirements 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. The more Medicare data that is publicly available, the more that data will be culled by marketers, journalists, whistleblowers, and others with their own agendas.

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.

CMS expresses some 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.

To address this concern, CMS proposes a new requirement under which EGWPs must 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.

Closer Scrutiny for Prescriber Enrollment in Medicare Part D

Beginning in January 2015, CMS intends to require all PDP sponsors and PBMs to deny pharmacy claims for Part D drugs if the physician or eligible provider who prescribed the drug is not an approved Medicare provider, except under limited circumstances. Drugs prescribed by non-enrolled providers will only be covered if the provider follows established opt-out procedures, which include filing an affidavit listing their NPI with a Medicare Administrative Contractor. Separately, CMS 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.

In response to criticism that CMS has failed to monitor excessive prescribing activity, 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 is, under the new rules, dependent on the enrollment status of the prescriber, CMS theorizes that revoking the prescriber's Medicare enrollment will result in non-coverage of the 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 Medicaid beneficiaries. What may be considered excessive narcotic prescribing for a relatively healthy 72 year old may not be excessive to a 72 year old suffering from chronic back pain, but, it is CMS and not the beneficiary or the physician who gets to decide what is excessive.

Regulatory Changes Specific to Long-Term Care

Recent health care enforcement efforts have exposed concerns regarding drug administration in long-term care settings. To promote "efficient dispensing" in long-term care, CMS is proposing multiple regulatory changes impacting PDPs and MA-PD plans that serve long-term care beneficiaries. CMS proposes to prohibit payment arrangements that "penalize the offering and adoption of more efficient LTC dispensing techniques," to establish a daily cost sharing rate, and eliminate language that led to the "misinterpretation" that dispensing fees could be prorated. CMS also proposes to waive short-cycle dispensing requirements under certain circumstances.

Other Program Integrity/Payment Accuracy Provisions

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

- 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 supplement 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;
- Establishing a RAC Appeals process for Part C and Part D RAC overpayment determinations;
- Requiring MA plans to have procedures in place to coordinate benefits under Parts A, B, and D;
- 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.

Changes and Guidance for Medicare Advantage Risk Adjustment

The MA Risk Adjustment system is complicated and constantly evolving. 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. In the proposed rules, CMS proposes changes regarding: (a) how MAOs should conduct reviews; (b) submission deadlines for risk adjustment data; (c) who can conduct an RADV audit; and (d) changes to the process an MAO uses to appeal CMS RADV Audit findings.

Medical Record Review

CMS proposes to 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. Ironically, CMS has been criticized in the past for designing audit processes that are designed to identify potential overpayments to MAOs, but not underpayments.

Submission of 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).

Who Can Conduct an RADV Audit?

Currently, only CMS may conduct RADV audits but CMS is now proposing that the Secretary of the Department of Health & Human Services may also conduct RADV audits. This is a significant departure from current practices and it appears as though such a change would invite other sub-agencies, such as the Office of Inspector General (OIG) of the Department of Health & Human Services into the field of RADV. The OIG has conducted audits relating to MA risk adjustment for years, but no agency, other than CMS, has previously been tasked with conducting RADV audits, in accordance with RADV regulations and guidance, and with recouping funds based on such audit findings.

RADV Appeals

CMS proposes many changes to the RADV appeal processes. Currently, MAOs that wish to appeal RADV findings have two separate appeal tracks depending upon the issue they would like to appeal, one that addresses medical record review determinations (two steps) and a separate process for appeals relating to the RADV payment error calculation (three steps). CMS now proposes to combine the processes and MAOs can 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. In order to be eligible to appeal, an MAO must adhere to established RADV audit and RADV appeal procedures and requirements.

During an 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. In the proposed rules, CMS now proposes to delete the term "the one best medical record" and gives almost no explanation for this proposed change. It appears that under the proposed rules, MAOs will continue to be able to submit multiple records to substantiate a diagnosis during an RADV audit, but when appealing an RADV audit medical record review determination, an MAO will only be permitted to submit one medical record for appeal and that it must be one of the records that had been submitted during the RADV audit. The proposed rules also seek to establish a burden of proof standard for medical record review determination appeals, something that has been lacking and inconsistent in RADV appeals processes. CMS now proposes that an MAO must demonstrate, based on a preponderance of the evidence, that CMS's determination was erroneous.

The proposed rules include additional changes and provide additional guidance on RADV payment error calculation appeals and what issues are not eligible for RADV Appeals generally. MAOs and all interested parties should carefully review the proposed changes and carefully consider how they may impact their current practices and what comments they should submit for CMS's consideration.

Major Changes for PBMs, Pharmacies, and Pharmacy Networks

Revised Definition of Negotiated Prices and Pharmacy Price Concessions

One of the more significant changes in the proposed rule relates to the definition of "negotiated prices" and CMS's interpretation of what falls within the scope of pharmacy price concessions.

Currently, "negotiated prices" are the prices that (i) the sponsor (or PBM) and the pharmacy have negotiated as the amount the pharmacy will receive in total for a particular drug, (ii) are reduced by discounts, subsidies, other price concessions, and direct and indirect remuneration (DIR) that the sponsor has elected to pass through to enrollees at the point-of-sale, and (iii) include any dispensing fees. While CMS intended clause (ii) above to refer primarily to prices concessions from parties other than pharmacies that were calculated at a later date (i.e., drug manufacturer rebates), it acknowledges in the proposed rule that the language is ambiguous and permits sponsors and PBMs to take price concessions from pharmacies in forms other than negotiated price and report these concessions outside of the PDE (i.e., in DIR reports). CMS believes that such activities increase negotiated prices, shift costs to the beneficiary, the government, and the taxpayer, and ultimately distort the true price of drugs available in the market.

CMS specifically identifies network access fees, administrative fees, technical fees, and rebated dispensing fees as examples of fees that sponsors and PBMs currently exclude from the determination of negotiated price, but which CMS considers to be price concessions and must be treated as such in Part D cost reporting. From CMS's perspective, if these fees are reported as DIR they offset price concessions disproportionately against costs that the plan is liable for and if the fees are not reported at all they result in PBM-spread in which inflated prices contain a portion of costs that should be treated as administrative costs, not drug costs. CMS further states that the failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus submit a lower bid than necessary to reflect its revenue requirements relative to another sponsor that accurately reported administrative costs.

CMS does acknowledge that generic dispensing incentive fees should not be included in negotiated prices because such incentive fees represent contingent price increases that cannot be predicted in advance and cannot be programmed to be applied at the point-of-sale or reflected in the price posted on Plan Finder. Such fees should be reported later in reconciliation as negative DIR.

Accordingly, the proposed rule redefines negotiated prices to require that all price concessions from pharmacies are reflected in these prices and states that the negotiated price must be "inclusive of all price concessions and any other fees charged to network pharmacies" but may exclude contingent amounts, such as incentive fees, if these amounts increase prices and cannot be predicted in advance. To address rebated dispensing fees, the definition specifies that the price may not be rebated back to the sponsor or PBM.

CMS Defines the Parameters of Contractual Non-Interference

CMS uses the proposed rule as an opportunity to provide a formal interpretation of the limits imposed on its authority under the so-called "non-interference" provision. This provision is intended to promote competition and prohibits CMS from (i) interfering with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and (ii) requiring a particular formulary or instituting a price structure for the reimbursement of Part D drugs.

CMS interprets the goals of this provision as promoting private market competition in the selection of Part D drugs for Part D sponsor formularies and prohibiting it from creating any policies that would interfere with competitive market negotiations leading to the selection of drugs to be covered under Part D formularies. To achieve these goals, the proposed rule provides that CMS may not be a party to discussions between drug manufacturers and pharmacies, or drug manufacturers and Part D sponsors, and may not arbitrate the meaning of or compliance with the terms and conditions of such agreements, except as necessary to enforce CMS requirements applicable to

those agreements. CMS states “we believe we should not pick winners and losers in formulary selection negotiations, and that the remedies for disputes should be determined in accordance with the terms of the contracts or in the courts having jurisdiction over the contracts.”

In contrast, CMS does not interpret the non-interference provision as applying to negotiations between Part D sponsors and pharmacies. CMS points to numerous statutory provisions that require it to directly intervene in the contractual relationship between sponsors and pharmacies such as the any-willing pharmacy standards, negotiated price requirements, and prompt payment rules. However, based on the requirements of the non-interference provision and to avoid distorting private market outcomes, CMS will decline to intervene in contractual disputes between sponsors and pharmacies, except in matters implicating CMS requirements.

With respect to formularies, CMS interprets the non-interference provision as prohibiting it from developing formulary guidelines that prefer one manufacturer’s product over another, thus leading to development of more limited formularies such as those utilized by the Department of Defense and the Veteran’s Administration. Specifically, CMS may not determine the specific drug products to be included on the formulary or any tier placement.

Finally, CMS further clarifies the scope of the non-interference provision by amending the rules to prohibit CMS from establishing drug price reimbursement methodologies, drug pricing standards, or the dollar level of price concessions at any stage in the drug distribution channel for Part D drugs. CMS may not require Part D drug acquisition costs or sales prices to be a function of any particular pricing standard (e.g., AWP, WAC, AMP, etc.) and it cannot require price concessions to be at any specific dollar amount or equal to a level specified in other legislative requirements for other federal programs (e.g., Medicaid).

CMS Expands Definition of Prescription Drug Pricing Standard to Include MAC Lists

Current Medicare Part D regulations require that a sponsor’s pharmacy network contracts include a provision establishing regular updates (i.e., every 7 days) of any prescription drug pricing standard used by the Part D sponsor and identifying the source used for such pricing updates. The regulations do not provide a specific definition for “prescription drug pricing standard.”

Based on conversations with the pharmacy industry and concerns regarding uncertainty associated with maximum allowable cost (MAC) pricing, CMS has decided to define “prescription drug pricing standard” and clarify that the updating requirement applies to pricing standards based on the cost of the drug, even when the standard (such as a MAC list) is not based on published drug pricing. CMS believes that there are risks to the Medicare Part D program if pharmacies cannot determine their reimbursement for all drugs and monitor pricing sources to ensure correct reimbursement. These risks would include the potential for inaccuracy of costs submitted to CMS and of prices displayed in the Medicare Prescription Drug Plan Finder.

CMS proposes to broadly define “prescription drug pricing standard” as “any methodology or formula for varying the pricing of a drug or drugs during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufacturer price, average sales price, maximum allowable cost (MAC), or other cost, whether publicly available or not.” CMS preempts comments as to what would not fall within this broad definition by stating that a fixed fee drug price schedule that does not vary during the term of the pharmacy contract would not be a “prescription drug pricing standard” as there would be no reason to update the list at least every 7 days.

CMS also proposes a new requirement that Part D sponsors agree in their contracts with CMS to disclose all individual drug prices to be updated to the applicable pharmacies in advance of their use for reimbursement of claims, if the source for the pricing standard is not publicly available. This means that Medicare Part D sponsors would have to convey to network pharmacies in advance the actual MAC prices to be changed.

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The End of Sponsor-Designed Preferred Networks and the Beginning of Any Willing Preferred Pharmacies

CMS questioned certain relationships between PDP Sponsors and their "preferred pharmacies" in its Contract Year 2014 Call Letter and now CMS has concluded that preferred networks: (a) do not consistently result in lower costs to Medicare Part D, and (b) can result in some beneficiaries not having access to the preferred pharmacies.

To address its first concern, CMS is proposing to delete the term "preferred pharmacy," introduce the term "preferred cost sharing" and require that a PDP that offers a *preferred cost-sharing* plan, only offer *preferred cost sharing* at pharmacies that agree to pricing levels that are less than the minimum price charged by pharmacies that are offering standard cost sharing (the term CMS uses for cost-sharing amounts charged by pharmacies that do not offer *preferred cost sharing*.). CMS wants *preferred cost sharing* to signal to beneficiaries that Medicare Part D is receiving lower prices as well. Specifically, PDP Sponsors would only be able to offer reduced co-payments at network pharmacies that offer "consistently lower negotiated prices [on] the same drugs when obtained in the rest of the pharmacy network." By "consistently lower," CMS means that sponsors must offer beneficiaries *and* the Part D program better (lower) negotiated prices on all drugs in return for the lower cost sharing.

To remedy its second concern, CMS proposes to require PDP Sponsors to offer all pharmacies the opportunity to offer *preferred cost sharing* if the pharmacy can offer the requisite level of negotiated prices. CMS is considering whether to require a minimum level of savings in order for a PDP Sponsor to offer *preferred cost sharing*. CMS is also soliciting comments on how broad *preferred cost sharing* should be applied to drugs on a sponsor's formulary. For example, should *preferred cost sharing* have to apply to a minimum percentage of formulary products or to all drugs available at pharmacies offering preferred cost sharing?

The proposed changes could result in a variety of scenarios. Will large pharmacies that have had "preferred" status lower their prices further to make it more difficult for other pharmacies to match the low prices? Will pharmacies that have not previously been offered "preferred" status be able to offer lower prices than those that have? Or, will pharmacies decide that they do not want to participate in what could be a race to the bottom?

Mail-Order Pharmacies

In its Final Call Letter for Contract Year 2014, CMS indicated that it was concerned about mail-order pharmacies filling one-month supplies of prescriptions. Specifically, CMS warned PDP Sponsors to expect CMS to deny benefit designs that include very attractive mail-service cost-sharing incentives for 30-day supplies unless the same cost sharing is available at retail pharmacies. CMS now proposes that for 30-day supplies, cost sharing at mail cannot be less than cost sharing at retail, so as not to provide an incentive to fill short supplies of chronic medications through mail-order pharmacies.

Additionally, to ensure consistent and reliable beneficiary access to mail medications, CMS proposes to establish mail order fulfillment requirements pursuant to which prescriptions must be shipped within (i) five business days from when the pharmacy receives the order for prescriptions that require intervention beyond filling (such as clarifying illegible orders, resolving third party rejections, and coordinating with multiple providers as part of drug utilization management), and (ii) three business days from when the pharmacy receives the order for those prescriptions that do not require intervention.

Medication Therapy Management

CMS believes that the Medication Therapy Management (MTM) programs improve quality and generate medical savings. Unfortunately, access to MTM remains very low, with MTM eligibility rates at less than eight percent (8%) in 2011. CMS seeks to increase access to these services by proposing changes to its interpretation of "multiple chronic diseases" to establish eligibility for beneficiaries with two or more chronic diseases, requiring only one of the chronic diseases to be on the core disease list, and lowering the annual cost threshold for participation. These changes will require PDP sponsors to target and provide MTM to a much larger portion of enrollees – CMS estimates approximately fifty-five percent (55%) of Part D beneficiaries will be eligible for MTM.

New Drug Coverage Requirements

Mandatory Part D Coverage of Drug Categories and Classes

CMS proposes to implement ACA requirements regarding changes to required Part D coverage of drugs within drug categories or classes of clinical concern. Currently, all PDP formularies must include "substantially all" drugs within six drug categories: (i) antineoplastics, (ii) anticonvulsants, (iii) antiretrovirals, (iv) antipsychotics, (v) antidepressants, and (vi) immunosuppressants. The proposed rules establish criteria that CMS will use to identify drug categories or classes of clinical concern from the existing categories and identify drug categories or classes that meet the proposed criteria, as well as exceptions that permit PDP sponsors to exclude certain Part D drugs within an identified drug category or class from their formularies.

New Criteria to Identify Drug Categories or Classes of Clinical Concern

CMS states that drug categories and classes of clinical concern should identify only those drugs for which access cannot be adequately ensured by other beneficiary protections. To this end, it proposes that all Part D drugs within a drug category or class (unless an exception applies) shall be included on the formulary if:

i. Hospitalization, persistent or significant incapacity or disability, or death likely will result if initial administration of a drug in the category or class does not occur within seven (7) days of the date the prescription for the drug was presented to the pharmacy to be filled; and

ii. More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

CMS proposes that the antiretroviral, antineoplastic, and anticonvulsant categories and classes meet these criteria because timely initiation of administration of such drugs generally cannot be delayed and different drugs within these categories are used in fact-determinant clinical settings such that an alternative formulary requirement is not feasible. CMS reserves its decisions regarding the antipsychotic drug class, and proposed it continue to be considered a class of clinical concern in 2015 pending further review. But under the rules, PDP formularies will no longer be required to include all Part D drugs in the antidepressant and immunosuppressant categories and classes.

Exceptions to Mandatory Drug Coverage Requirements

CMS includes several exceptions to the requirements that all Part D drugs in categories and classes of clinical concern be included in a PDP formulary. CMS retains the exception for therapeutically equivalent drug products and, among others, creates exceptions for drug products covered under Medicare Parts A or B, Part D compound drugs, and FDA-approved fixed-combination dosage form drug products that include at least one Part D drug, and multi-source drugs that do not provide a unique route of administration. CMS seeks comments on possible exceptions to allow PDP sponsors to implement prior authorization to convert beneficiaries to preferred alternatives within the drug categories of clinical concern for enrollees initiating new therapy.

Transition Coverage

In order to reduce confusion and assure consistent treatment of formulary and non-formulary drugs, CMS clarifies the requirements for cost sharing when a Part D plan enrollee transitions from other prescription drug coverage. For a temporary supply of drugs provided during transition, the proposed rules require a PDP sponsor to charge low-income subsidy (LIS) enrollees cost sharing that is no higher than the statutory maximum co-payment amounts. For non-LIS enrollees, the PDP sponsor must charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception, and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

Conclusion

Clearly, there is a lot to digest in these rules. We will be sending you an invitation to our January 29th webinar to discuss the implications of these rules and potential areas for comment. We hope you will join us.

» Register for the webinar here.

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