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CLIENT ALERT

CMS Proposes Far-Reaching Changes to the Medicare Part D Prescription Drug Benefit Program and the Medicare Advantage Program

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On January 10, 2014, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule ("Proposed Rule") setting forth sweeping changes to the Medicare Program's outpatient prescription drug benefit ("Part D") program and additional changes to the Medicare Advantage ("MA") program. Comments are due by 5 p.m. ET on March 7, 2014.[1] Stakeholders comprise a wide range of organizations, including managed care organizations, prescription drug plan sponsors, pharmacy benefit managers, pharmacies, drug manufacturers, and the vendors that provide services and products to this segment of the health care industry. Stakeholders are urged to comment on the Proposed Rule. Please visit http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf for more information about how to submit comments. Stakeholders will be significantly affected if the provisions in the Proposed Rule are adopted as proposed.

Significantly, CMS expects to have the provisions in the Proposed Rule take effect for the 2015 contract year notwithstanding the fact that the proposals were only first published on January 10 and still must be incorporated into a final rule. This is a very tight time frame for rulemaking given the annual application and bidding deadlines.

PROPOSED PROVISIONS AFFECTING BOTH THE OUTPATIENT PRESCRIPTION DRUG PROGRAM & THE MEDICARE ADVANTAGE PROGRAM

Role of CMS in Negotiations & Disputes Between Drug Manufacturers, Pharmacies, and Plans

A cornerstone provision in the Outpatient Prescription Drug Benefit law that was enacted as part of the Medicare Modernization Act of 2003 is the noninterference provision. The noninterference provision prohibits the Secretary of CMS from interfering

[1] Interested parties can submit comments to CMS at http://www.regulations.gov/#!home.

with negotiations between drug manufacturers, pharmacies, and sponsors of prescription drug plans—the purpose of the provision, as stated in the statute, is "to promote competition under [Part D]."[2]

For many years, CMS has refrained from interfering in this area. However, in the Proposed Rule, CMS is proposing to change its position regarding the scope of CMS's limitations in this area and then codify that new CMS position into a new federal regulation. The provision in the Proposed Rule would only prohibit CMS from being a party to negotiations between drug manufacturers and pharmacies, or between drug manufacturers and Part D plan sponsors, and from arbitrating disputes concerning the terms and conditions of agreements between those parties. The provision in the Proposed Rule would no longer prohibit CMS from playing a role in negotiations between Part D plan sponsors and pharmacies. Indeed, there are several potential new regulations designed to have CMS regulate the negotiations between Part D plan sponsors and pharmacies. Stakeholders should review and comment on this significant change in position for CMS.

In addition, the statute prevents CMS from requiring that plans have a particular formulary or instituting a price structure for the reimbursement of Part D covered drugs. The Proposed Rule includes a provision that defines the scope of this prohibition. For example, it states that CMS may not determine the specific drug products to be included on Part D sponsor formularies or the tier placement of such products, and CMS may not establish specific methodologies, formulas, or dollar amounts of price concessions. However, CMS is taking the position that the noninterference statutory provision does not limit CMS's authority to promulgate rules that affect the negotiations between Part D plan sponsors and pharmacies such as mandating full disclosure or uniform treatment and reporting of drug costs and prices. CMS states that this authority allows it to establish rules such as how drug costs are disclosed in the marketplace, how they are made available to beneficiaries at point of sale and reported in an Explanation of Benefits, and how they are disclosed to CMS.

Overpayment Reporting and Return Provisions

The Proposed Rule addresses the requirements added by the Affordable Care Act for MA plans and Part D plans to report and return an overpayment within 60 days after the overpayment is identified. For example, the Proposed Rule would provide that an overpayment exists when the MA plan or Part D plan has funds that it is not entitled to after reconciliation. (For MA plans, the reconciliation period ends on the final deadline for submission of risk adjustment data; for Part D plans, reconciliation ends on the later of: (i) the annual deadline for submitting prescription drug event data for annual payment reconciliations or (ii) the annual deadline for submission of direct and indirect remuneration ("DIR") data.)

The Proposed Rule would provide that an overpayment has been identified when an MA organization or Part D sponsor has actual knowledge of the existence of an

[2] 42 U.S.C. § 1395w-111(i)(1) (2012), *available at* http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap7-subchapXVIII-partD-subpart2-sec1395w-111.pdf.

overpayment, or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. This is consistent with proposed overpayment rules that apply to the providers and suppliers under Medicare Parts A and B.

Moreover, the Proposed Rule would specify that, if an MA organization or Part D sponsor receives information that an overpayment might exist, the organization must exercise reasonable diligence to identify whether there has been an overpayment. In addition, CMS states that the MA organization or Part D sponsor is deemed to have satisfied the 60-day rule if it notifies CMS and takes other actions that CMS specifies to submit corrected data. CMS generally will recover overpayments through its routine processing. CMS states that (except in cases of fraud) the look-back period for the reporting and return of overpayments is the six most recent completed payment years.

CMS Authority to Require Independent Audits

CMS proposes to require that MA organizations and Part D sponsors hire and pay for an independent auditor to perform full or partial program compliance audits of their own Medicare Part C or D products. In the past, CMS conducted program audits. CMS states that with the proposed approach, each MA organization and/or Part D sponsor will undergo an independent program audit at least every three years. The Proposed Rule also would specifically permit CMS to require MA organizations or Part D sponsors with audit results that reveal non-compliance to hire an independent auditor to validate that corrective action has occurred.

CMS is making this proposed change so that it might have greater oversight resources available for adherence to requirements established by statute, regulation, and sponsor contracts without incurring any additional costs. In contrast, MA organizations and Part D sponsors would shoulder the costs and burdens of these increased audits.

Recovery Audit Contractor Appeals Process

The Proposed Rule would establish an administrative appeals process to challenge overpayment findings in the Part C and Part D programs made by recovery audit contractors ("RACs"). The Proposed Rule sets forth in detail the rights and requirements of plans in a three-level appeals process, including: (1) reconsideration of the decision by an independent reviewer, (2) review by a CMS hearing official, and (3) discretionary review by the CMS Administrator.

The creation of an appeals process will afford MA plans and Part D sponsors a level of transparency and consistency when they contend that a decision was made in error and seek to have it reversed.

CMS Authority to Request Information from FDRs Directly

The Proposed Rule would explicitly allow CMS, by regulation, to "collect" records directly from an MA plan's or Part D plan's first tier, downstream, or related entity ("FDR"), in addition to the existing authority that CMS currently has to audit, inspect,

and evaluate information held by FDRs. CMS also could contact the FDR directly to obtain the information. The Proposed Rule would require that CMS notify the MA or Part D plan at the same time that CMS contacts the FDR.

Modifications to Requirements for Independent Agents & Brokers

The Proposed Rule changes existing requirements on the compensation structure for agents and brokers selling MA plans and Part D plans. Specifically, the Proposed Rule would require that MA organizations and Part D plan sponsors pay renewal compensation up to 35 percent of the current fair market value ("FMV") for agent/broker services, with such amounts to be published annually by CMS. Thus, the renewal year compensation would be tied to FMV in the year of renewal, rather than be 50 percent of the compensation in the initial year of enrollment as provided under current rules. Certain other requirements are also proposed (e.g., with respect to the timing of compensation payments).

PROPOSED PROVISIONS AFFECTING THE OUTPATIENT PRESCRIPTION DRUG PROGRAM

Preferred Network Pricing

Currently, Part D plans can offer Medicare beneficiaries lower cost sharing at a limited number of "preferred" network pharmacies. Under the Proposed Rule, CMS would impose several important changes to the operation of these "preferred" network pharmacies.

First, Part D sponsors could continue to offer Part D plans with reduced Medicare beneficiary cost sharing in a "subset of network pharmacies, as long as such preferred cost sharing is offered . . . with *consistently lower* negotiated prices than . . . the rest of the pharmacy network." CMS is proposing in the Proposed Rule that "consistently lower" would mean the pharmacies with preferred cost-sharing rates will have deeper discounts on all drugs as compared to other network pharmacies. In the Proposed Rule, CMS is also soliciting comments from the public as to whether CMS should establish a minimum-level-of-savings requirement for preferred cost-sharing rates (e.g., mandatory 15 percent or greater savings for preferred cost sharing than standard cost sharing) and whether the preferred cost sharing should apply to a minimum percentage of formulary products.

Second, the Proposed Rule would provide that any pharmacy willing to accept a Part D sponsor's lower reimbursements and other terms and conditions must be allowed to be part of the "preferred" cost-sharing network.

Third, the Proposed Rule would eliminate preferred pricing for one-month supplies filled by mail-order pharmacies.

The changes included in the Proposed Rule could have a significant impact on the current, rapid growth of "preferred" pharmacy networks.

"Negotiated Price" Expanded to Include Pharmacy Price Concessions

Currently, Part D sponsors may receive price concessions from pharmacies in the form of administrative or other fees that are reported as DIR rather than reported on a prescription drug expense report as part of the drug's "negotiated price." The Proposed Rule would re-define "negotiated price" to include "all price concessions and any other fees" from network pharmacies. Price concessions from pharmacies that could not be calculated at point of sale would be eliminated. However, additional contingent payments to pharmacies that cannot be predicted in advance, such as fees paid by Part D sponsors to incentivize generic drug dispensing, would be permitted. Such additional contingent payments would be reported as DIR.

These changes in the Proposed Rule, if adopted as final, could have a significant impact on future bids and on the overall costs for the Part D program.

Maximum Allowable Cost Pricing Updates

If, to reimburse pharmacies for covered drugs, a Part D plan uses a "prescription drug pricing standard" methodology based on the cost of a drug, then the pricing standard generally must be changed no less frequently than every seven days. In the Proposed Rule, CMS is proposing to modify these existing rules to specify that any methodology based on drug cost, whether the cost is publicly available or not, must meet this seven-day requirement. This would include prescription drug pricing methodologies based on maximum allowable cost ("MAC"). In the Proposed Rule, CMS is also proposing to require that Part D plan sponsors disclose all drug price updates (including MAC prices) to pharmacies in advance of the sponsor's use of these pricing updates for reimbursement if the source of the prescription drug pricing standard methodology is not publicly available.

Expansion of Medication Therapy Management Programs

In the Proposed Rule, CMS is proposing to change the Medication Therapy Management ("MTM") programs required to be offered by Part D plans. These proposed changes are expected to increase MTM participation by enrolled Medicare beneficiaries. Currently, for MTM programs, Part D plans are required to target enrolled Medicare beneficiaries meeting three criteria: (1) having multiple chronic conditions, (2) using multiple covered Part D drugs, and (3) having annual costs exceeding a certain level. The current dollar target threshold is $3,017.[3]

The Proposed Rule would change MTM eligibility criteria by requiring Part D plan sponsors to target Medicare beneficiaries (i) who have two or more chronic diseases, with at least one being from a list of chronic diseases specified in the Proposed Rule, (ii) who are taking two or more Part D drugs, and (iii) who are likely to incur annual Part D drug costs exceeding $620 (such number to be adjusted in future years).

[3] CMS, Contract Year 2014 Final Call Letter 165 (Apr. 1, 2013), *available at* http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf.

Furthermore, CMS stated that it expects Part D sponsors to conduct outreach to enrolled Medicare beneficiaries in order to obtain information about their use of over-the-counter medications. Finally, the Proposed Rule would require that Part D plan sponsors "have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan." CMS is specifically soliciting comments from the public on alternative thresholds that might be considered in this context.

Mail-Order Fulfillment Requirements

The Proposed Rule requires mail-order pharmacies (and retail pharmacies offering home delivery services) to ship a prescription within three business days of receipt of an order, or within five business days if some form of intervention is required beyond just filling the prescription. CMS acknowledges that certain orders may require additional steps that take more than five days but expects that more than 99 percent of prescriptions will be filled in compliance with the proposed time frames. CMS is specifically soliciting comments from the public on whether CMS should establish additional requirements for Medicare beneficiary materials relating to mail service deliveries. CMS is also requesting comments on other potential changes to mail order and other home delivery options, including restrictions on fills of initial prescriptions or 30-day supplies. And, as stated above, the Proposed Rule includes a proposed provision that would eliminate preferred pricing for one-month supplies filled by mail order.

Limiting Criteria on Drug Categories or Classes of Clinical Concern

In general, all drugs in classes of clinical concern must be included on a Part D plan's formulary. The Proposed Rule will codify two new criteria, both of which would have to be satisfied for the particular drug to be included in a class of clinical concern. Under this new proposed criteria, for a typical patient with a condition to be treated by such drugs: (1) hospitalization, disability, or death are likely to result within seven days of a prescription being presented if that prescription is not filled; and (2) more specific formulary requirements cannot adequately address the total possible drug-and-disease-specific applications necessary for treatment in the category or class. The Proposed Rule also will increase the types of exceptions currently available to Part D plans for excluding coverage of certain drugs in a class of clinical concern, including through point-of-sale safety edits that are consistent with the FDA-approved label (e.g., maximum daily doses and black-box warnings), for drugs almost always covered under Parts A or B, through prior authorizations to determine whether a drug is for a medically accepted indication or to verify that the drug is not covered under Medicare Parts A or B, for Part D compounds, for fixed-dose combinations other than antiretrovirals, and for certain other types of drug products. CMS also is specifically soliciting comments on continuing to allow prior authorization for these drugs (other than HIV/AIDS drugs), including step therapy, to convert Medicare beneficiaries who may be just starting a therapy to a preferred alternative.

Based on the proposed new criteria, only three of the six existing protected classes would remain—anticonvulsants, antineoplastics, and antiretrovirals—and no additional

classes would qualify. Drug manufacturers would likely face pressure to negotiate price concessions for formulary placement for antidepressants and immunosuppressants for transplant rejection, since Part D sponsors are no longer required to include all drugs in these classes on Part D plan formularies. CMS will continue to treat the antipsychotic drug class as a class of concern in 2015 while CMS continues its assessment, even though CMS says that antipsychotics do not meet both of the new proposed criteria.

Limitation of Prescription Drug Plans per Region

The Proposed Rule would give CMS new authority to deny the application for a stand-alone Part D plan in a region if another subsidiary of the applicant's parent organization already has a contract in the same region. In addition, effective for 2016, Part D sponsors would be limited to offering no more than two stand-alone Part D plans in each region—one basic and one enhanced. Additionally, CMS is specifically soliciting comments on three alternative routes under consideration to mitigate risk segmentation practices in prescription drug plans. One option would require that an enhanced Part D plan be subject to a minimum level of supplemental coverage in the form of reduced cost sharing and deductibles and the inclusion of drugs excluded on the sponsor's basic Part D plan. An alternative consideration is to require that enhanced Part D plans provide premiums equal to or lower than the Part D sponsor's basic plan premium or that an enhanced Part D plan premium be no less than a specific multiple of the basic premium. The third alternative would redefine enhanced coverage to consist of supplemental coverage added to a Part D plan sponsor's one basic benefit offering for an additional premium.

Parent organizations will have to meet plan performance measures, state licensure requirements, and other trademark licensing provisions by means other than the use of different Part D sponsors to offer unique benefit packages. Part D sponsors will need to reconsider plan offerings to meet standards of enhanced plan offerings efficiently, and they may find that such offerings are not conducive to their business models.

Required Enrollment for Part D Prescribers

The Proposed Rule would require a prescriber of Part D drugs to be enrolled in the Medicare fee-for-service ("FFS") program. Alternatively, physicians and eligible professionals that furnish services on a private contracting basis would be able to opt out of enrollment but still prescribe Part D drugs if they furnish an affidavit containing their national provider identifier ("NPI") to a Part A or Part B Medicare Administrative Contractor ("A/B MAC"). CMS would provide Part D plan sponsors with a list of all eligible prescribers. CMS is specifically seeking comments from the public on whether all pharmacies should be required to enroll in the Medicare FFS program in order to dispense covered drugs to enrolled Medicare beneficiaries.

Prescribers would be required to enroll by January 1, 2015. Prescribers must verify their credentials and disclose professional discipline and criminal history during the enrollment process. Additionally, prescriptions written by prescribers outside the United States or a U.S. territory would no longer be valid under Part D. As a result of the

change, Part D sponsors would no longer be tasked with determining a prescriber's eligibility based on an active and valid NPI.

Provisions Aimed at Potential Fraud & Abuse

The Proposed Rule includes several changes aimed at reducing potential fraud and abuse. For example, the Proposed Rule would authorize CMS to deny or revoke a physician's enrollment in the Medicare Program if the physician has a pattern or practice of prescribing Part D drugs that is "abusive and represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements."[4] CMS also would have new authority to deny or revoke a physician's Medicare enrollment if the physician's DEA Certificate of Registration or applicable state license to prescribe is suspended or revoked. Prescribers also will no longer be able to prescribe Part D non-controlled drugs where their DEA Certificate of Registration has been suspended or revoked.

Furthermore, under a separate proposal, prescriptions written by providers, such as chiropractors, social workers, physical therapists, registered nurses, occupational therapists, and speech pathologists, will no longer be covered unless the provider enrolls in the Medicare FFS program or formally opts out of enrollment and furnishes an affidavit containing the person's NPI to an A/B MAC.

CMS is specifically soliciting comments from the public on whether the proposed criteria are appropriate, whether certain criteria should be given more weight than others, and whether these program integrity provisions should be expanded to include pharmacies.

PROPOSED PROVISIONS AFFECTING MEDICARE ADVANTAGE

Medical Record Reviews

The Proposed Rule would require that MA organizations design medical record reviews to determine the accuracy of diagnoses submitted for risk adjustment purposes. In the preamble to the Proposed Rule, CMS states that MA organizations would be prohibited from designing medical record reviews that are used only to identify diagnoses that would trigger additional payments from CMS. The reviews must be designed to identify errors in diagnoses submitted to CMS regardless of whether the errors would result in positive or negative payment adjustments. The Proposed Rule also provides that the MA plan's submission of risk adjustment data to CMS after the deadline would only be permitted to correct overpayments. Additionally, the Proposed Rule deletes the January 31 regulatory deadline for the MA plan to submit its final risk adjustment data to CMS for the prior payment year. Instead, CMS would announce the deadline that will be applicable for each year.

[4] 79 Fed. Reg. 1986 (proposed Jan. 10, 2014) (to be codified at 42 C.F.R. § 424.535(a)(14)).

Modifications to the Risk Adjustment Data Validation Appeals Process

The Proposed Rule would revise the risk adjustment data validation ("RADV") appeals process in several ways. For example, the proposed changes would consolidate the process for medical record review determination appeals and RADV payment error calculation appeals. The combined process would have three administrative steps: reconsideration, hearing officer review, and CMS administrator-level review. The Proposed Rule specifies that the Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits. In addition, an MA plan would need to demonstrate that CMS made an error, based on a preponderance of the evidence, in the MA plan's appeals.

These provisions in the Proposed Rule would increase the burden that MA organizations already have to succeed on the appeal of an RADV payment error determination. MA plans may no longer pursue certain appeals as a result of these proposed changes.

Star Ratings in MA-PD Plans

The Proposed Rule would establish that an MA organization offering a prescription drug benefit ("MA-PD") would be subject to termination for failure to achieve for three consecutive years at least three stars in ***both*** its Part C and Part D ratings in the same year. The current rule allows an MA organization to have a Part C or Part D star rating below three stars in a given year so long as that separate Part C or Part D rating is not below three stars for three straight years.

In addition to the provisions that we highlighted above, CMS is also proposing substantial changes in the following additional topics:

- Experience & Competency Requirements for New Applicants/Sponsors
- Business Engagement & Continuity Requirements for MA Organizations & Part D Sponsors
- Authority of CMS to Impose Intermediate Sanctions & Civil Monetary Penalties
- Grounds for Contract Termination & Implications
- Compliance Program Training Burden – Reduction
- Agent/Broker Training & Testing Requirements
- Administration of the Coverage Gap Discount Program
- Coverage Restrictions for Skilled Nursing Facility Stays
- Reward & Incentive Program Standards
- Standards for Efficient Dispensing in Long-Term Care Facilities
- Cost-Sharing Structure Applicable to Transitional Supplies
- Definition of a Part D Drug
- Responsibilities in Disasters & Public Health Emergencies
- Provision of Explanation of Coverage & Annual Notice of Change
- Coordination of Benefits Under Part A, Part B & Part D
- Conflicts in Pharmacy & Therapeutics Committees

- Use of Information Under Part D
- Individual Enrollment Requirements Specifying Lawful Presence & Incarceration Status

CONCLUSION

Stakeholders will be significantly affected if the provisions in the Proposed Rule are adopted as proposed. Consequently, managed care organizations, sponsors of prescription drug plans, pharmacy benefit managers, pharmacies, drug manufacturers, and the vendors that provide services and products to this segment of the health care industry are urged to comment on the Proposed Rule.

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This Client Alert was authored by **Mark E. Hamelburg, S. Lawrence Kocot, Thomas E. Hutchinson, Alan J. Arville,** *and* **Danielle L. Steele***. 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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