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CMS Proposes Major Changes to Medicare Part C and Part D



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On Jan. 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. Extensive comments are expected to be submitted by the deadline of March 7, 2014. The proposed rules contain many changes that will materially alter the operations of Medicare Part C and Part D.

The rules include provisions that impose limitations on Medicare plan participation and expansion; impact the agent/broker relationship and compensation structure; change mandatory coverage of certain drug classes; affect the creation and operation of pharmacy networks; create transparency in drug pricing and price reporting; alter the risk adjustment data validation process; and address program integrity issues.

If adopted as drafted, these rules will significantly impact how Medicare Advantage Organizations (MAOs) 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.

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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 MAO and PDP sponsor participation.

Imposing Limits on MA Contracts

The proposed rules expand CMS's authority to deny any contract or service area expansion to any MAO that has mutually terminated a contract or has elected not to renew a Medicare contract with CMS, 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.

The commentary accompanying the proposed rules reflects that CMS is concerned about MAOs that have their contract terminated for low enrollment, and then apply for a new contract with substantially the same plan. The proposed changes will 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. The rule is intended to prevent MAOs from moving 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. The proposed rules broaden the 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.

Imposing Limits on Medicare Part D Contracts

The proposed rules require an entity seeking to contract as a PDP sponsor, or an MAO offering Part D benefits, or it's 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 will have to 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 have 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.

CMS is using the proposed rules to rein in the number of Part D plans offered and the number of entities offering those plans.

Throughout commentary published with the proposed rules, 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).

CMS is using the proposed rules to rein in the number of Part D plans offered and the number of entities offering those plans. According to CMS, ''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.''

Expanding Star Rating Terminations

Currently, MAO plan sponsors and PDP sponsors receive plan ratings, or ''star ratings,'' on a 1 star to 5 star scale, that are used as both a beneficiary educational tool and as part of CMS's quality control efforts. Under the Affordable Care Act (ACA), MAO plan sponsors may 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 fails to achieve at least a 3-star summary plan performance rating for three consecutive contract years, theorizing 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.

But MA-PD organizations receive a star rating score based on their Part C operations and a separate star rating score for 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 one of 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.

Similarly, under current authority it is possible 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

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D ratings became unsatisfactory. The proposed rule closes that loophole and would be effective upon the release of the 2015 star ratings in September 2014.

Simplifying Agent/Broker Compensation and Relationships

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.

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.

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The proposed rules purport to ''simplify'' the compensation structure and eliminate what CMS views as 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 proposed rule removes the current six-year cap on the agent/broker compensation cycle.

The proposed rules also change other aspects of the agent/broker relationship, including:

- Clarifying 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.
- Prohibiting payments to agents/brokers before January 1 of the compensation year and requiring that payments be paid in full by December 31 of the compensation year. 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.
- Changing rules regarding recovery of compensation resulting from disenrollment. Plan sponsors must 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 takes place within the first three months and the disenrollment does not result (or could not have resulted) from an agent/broker's behavior, the plan sponsor will not be required to recover the compensation from the agent/broker.
- Limiting 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.
- Revising 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.

Changing Drug Coverage Requirements

Revising the Standards for Mandatory Coverage of Drug Categories and Classes

The proposed rules change the requirements governing Part D coverage of drugs within drug categories or classes of clinical concern. Current rules require that all PDP formularies include on formulary ''substantially all'' drugs within drug categories that are considered classes of critical concern, unless specified exceptions apply. Six classes currently meet that standard: (i) antineoplastics, (ii) anticonvulsants, (iii) antiretrovirals, (iv) antipsychotics, (v) antidepressants, and (vi) immunosuppressants.

The new rules create a two-prong test that CMS will use for identifying when a drug category or class is of clinical concern, triggering coverage of substantially all drugs in that category or class:

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.

Applying the new test to the five existing drug categories, CMS found 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. The result is that

all drugs in those three categories will have to be on PDP formularies, unless an exception applies.

CMS further found that the antidepressant and immunosuppressant categories and classes do not meet the test, meaning that all drugs in those two categories would no longer have to be on every plan formulary. CMS made no determination regarding the antipsychotic drug class, and proposed that it continue to be considered a class of clinical concern in 2015 pending further review and comment.

There are existing exceptions to mandatory coverage requirements, which CMS expands through the proposed rules. The rules retain the exception for therapeutically equivalent drug products and create additional exceptions, including:

- 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.

In commentary to the proposed rules, CMS solicited comments on potential additional exceptions, such as allowing PDP sponsors to implement prior authorization to convert beneficiaries to preferred alternatives within the drug categories of clinical concern for enrollees initiating new therapy.

Establishing New Rules for Transition Coverage

In order to reduce confusion and assure consistent treatment of formulary and non-formulary drugs, CMS proposes new language on 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.

Changing the Landscape for PBMs and Pharmacies in Part D

The new rules would markedly change how PBMs and pharmacies operate under Part D.

Restricting the Use of Preferred Pharmacy Networks

In its Contract Year 2014 Call Letter, CMS questioned certain relationships between PDP Sponsors and their ''preferred pharmacies.'' CMS has now 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.

In the proposed rules, CMS deletes the term ''preferred pharmacy,'' introduces the term ''preferred cost sharing'' and requires 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.

The rules further 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?

Defining 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

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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).

Imposing Standards for 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. Under the proposed rules cost sharing for 30-day supplies 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, the proposed rules establish mail order fulfillment requirements, including that 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.

Revising the Definition of Negotiated Prices

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.

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.

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.

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 that cannot be predicted in advance.

CMS acknowledges 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. To address rebated dispensing fees, the definition in the proposed rules specifies that the price may not be rebated back to the sponsor or PBM.

Creating Pricing Transparency and Releasing 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.

In the proposed rules, CMS broadly defines ''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.

The new rules would require 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.

Expanding Medication Therapy Management

In commentary accompanying the proposed rules, CMS maintains that Medication Therapy Management (MTM) programs improve quality and generate medical savings, and therefore CMS is looking to increase MTM program eligibility.

The proposed rules expand MTM eligibility to beneficiaries with two or more chronic diseases as long as one of the chronic diseases is on the specified core disease list and lower 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 under the new rules.

Changing 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 again change the process.

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 Department of Health & Human Services may also conduct RADV audits. This is a departure from current practices and 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 previously has conducted audits relating to MA risk adjustment, but no entity, other than CMS, has previously 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

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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 an RADV audit but will only be permitted to submit 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.

Addressing Payment Accuracy and Program Integrity

The proposed rules contain a myriad of provisions aimed at improving payment accuracy and correcting perceived program integrity issues in Medicare Parts C and D. If enacted as drafted, various rule provisions would:

- Establish citizenship and legal presence as beneficiary enrollment requirements;
- Allow MAOs to offer reward and incentive programs to current beneficiaries under specified conditions;
- Expand the limits on beneficiary premium and copayment waivers;
- Prohibit coverage of prescriptions written by non-enrolled and non-approved Medicare providers;
- Establish administrative and false claims liability for failure to report and return identified overpayments within 60 days;
- Impose new limits on arrangements involving long term care facilities;
- Change the provisions governing MAO training for downstream and related entities;
- Establish new reporting requirements for EGWPs;
- Provide CMS and its designees direct access to records from downstream entities;
- Require plans to hire independent auditors to perform full, partial and validations audits;
- Require PDP P&T Committees to address conflicts of interest;
- Establish a RAC appeals process;
- Expand the release of Part D data;
- Expand CMS authority to revoke provider's Medicare enrollment status;
- Shorten the notice requirement for CMS proposed contract terminations; and
- Expand CMS civil monetary penalty authority.

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.

In addition, the proposed timing under the rules appears to be unrealistic. Given the comments and controversy generated so far, it is unlikely that CMS will finalize these rules before the winter of 2014, at the earliest, yet many of the provisions in the proposed rules are drafted to be effective in 2015. Such an effective date will be difficult for plans and contractors that need sufficient lead time to design and implement the new systems and structures required by the proposed rules. All interested parties will need to carefully monitor developments while CMS sifts through all the submitted comments and contemplates the feasibility of its proposals.