AMCP Summary: CMS 2015 Medicare Part D Proposed Rule

Released: January 6, 2014

Comments due: March 7, 2014

Below is AMCP’s summary of the proposed 2015 Medicare Part D proposed rule (42 CFR Parts 409, 417, 422, 423, and 424) released by the Centers for Medicare and Medicaid Services (CMS) on January 6, 2014 and published in the Federal Register on December 10, 2014. CMS’ financial analysis of the major provisions projects health care savings of $1.34 billion over the period 2015-2019. The proposal contains sweeping Medicare Part D changes that will significantly impact AMCP members. The summary is not necessarily arranged in the order presented in the proposed rule but rather, issues are grouped topically for more clarity.

Please note specific areas of the summary designated as “AMCP Comment Opportunity” where questions are posed to members as a starting point on feedback for comment development. You are welcome to provide feedback on comments on any section and respond to any issue and even if questions are not included, AMCP could submit comments on that section. AMCP will consider your feedback for inclusion in comments. Please refer to the letter listed before each section when you provide feedback to AMCP.

If you would like to provide feedback to AMCP for comments, please email mcarden@amcp.org by 5 pm EST on Thursday, February 27, 2014.

A. Changes to Requirements for Managing Medications Considered Classes of Clinical Concern and Revisions to Medications in the Existing 6 Protected Classes (p 1936)

This provision is considered to be one of the major provisions of the proposed rule and substantially changes the manner in which plans may manage clinically protected classes of Part D medications. The proposal establishes the following objective criteria for whether a medication should be included in as a class of clinical concern:

- Initial administration would be required in less than 7 days of the date of the prescription and the coverage determination and appeals process would not properly provide for independent review and determination within that time frame, and failure to provide the medication would likely lead to hospitalizations, incapacity, disability or death; and,
- CMS cannot ensure that a formulary containing anything less than all medications would be sufficient to treat diseases or conditions in that class.
In addition to the criteria described above, CMS will also consider the existing beneficiary protections in determining whether classes or categories require further protection. These protections are:

- Formulary transparency, including publicly available formulary listings on plan websites and the CMS Plan Finder tool.
- Each plan’s formulary is subject to review that includes the following elements:
  - Discrimination review to ensure plan coverage sufficiency of medication choices;
  - Formularies must include at least 2 drugs from each category and class with limited exceptions;
  - Overall review of medications generally covered by plans to ensure consistency of formularies among plans, including a separate review for medications used in long-term care (LTC);
  - Review of standard treatment guidelines, including formulary review to ensure coverage of a specific medication if necessary;
  - Review of formularies for commonly used home infusion medications;
  - Vaccine coverage;
  - Insulin supplies;
  - Specialty tier review to ensure compliance with current requirements established each year by the CMS Medicare Part D Call Letter;
  - Analysis of quantity limits and a determination if outliers exist;
  - Appropriate use of step edits and PA;
  - Restrictions on mid-year formulary changes except in certain circumstances.
- Annual notice to reassigned beneficiaries of formulary changes and information on grievances and rights of appeal, including additional protections for individuals who are eligible for the low-income subsidy (LIS).
- Transition supplies and notices for new enrollees at the beginning of a plan year; for individuals who change coverage or experience formulary changes; and individuals who receive temporary fills within the first 90 days of enrollment in a new plan.
- Coverage determination and appeals process, including the exceptions process.

Even when medications are included in classes of clinical concern, CMS provides the following exceptions to the requirements for inclusion of all or substantially all products on the formulary:

- Medications listed in the Food and Drug Administration’s “Orange Book” determined to be therapeutic equivalents will be considered the same for Part D purposes and thus a formulary does not have to offer all equivalents.
- CMS will provide exceptions allowing for utilization management edits based on maximum daily doses and black-box warnings.
- Products almost always covered under Medicare Part A or B.
- Prior authorization (PA) is permitted to determine whether a Part D medication is used for a medically accepted indication or to verify coverage under Medicare Part A or B.
- Compounded formulations for products in the protected classes are not required for inclusion.
- Combination products where all single agent products are included. (CMS will retain the requirement that antiretroviral agents continue to be available as combination and co-packaged products.)
Exclusion of multi-source brands of identical molecular structure, extended release products when immediate release is available and products with the same active ingredient or chemical moiety, and dosage forms that do not provide a unique route of administration. (CMS believes that adherence to these products may be achieved through use of medication therapy management (MTM) or the use of special packaging.)

PA, including step therapy, may be used for newly initiated therapy, but not for purposes of converting to preferred alternative brand name products or for medications used for HIV/AIDS.

CMS’ rationale for the exclusion is that efficient formulary requirements or other beneficiary protections would suffice instead of mandating coverage of all medications in the class. The proposed policy suggests that medication categories and classes should be subject to normal formulary and price competition unless CMS cannot ensure that clinically appropriate, non-discriminatory access and benefit design would result from exclusion of certain medications. CMS’ own research suggests that all Part D covered medications are included on at least one plan formulary, and therefore, beneficiaries will likely have access to plans that include all of their medications.

**AMCP Comment Opportunity**

- AMCP has supported changes in the clinically protected class policy and would like feedback on the proposed requirements.
- Should CMS consider other criteria when establishing whether a medication should be included in a protected class?
- Does the new criteria proposed set an unreasonable standard for determining whether a class receives protection? What else should CMS consider?

**CMS Proposed Changes to Management of Medications in the Existing 6 Protected Classes**

Commentary in the proposed rule explains that the rationale for inclusion of the 6 protected classes in the beginning of the Medicare Part D program was to primarily ensure that dual-eligible beneficiaries, previously enrolled in Medicaid and not accustomed to managed medication benefits through health plans, would receive necessary and appropriate medications without confusion upon implementation of a new program. CMS notes that this situation has changed and that dual-eligible individuals have since become experienced in working with the Medicare Part D program and thus the need for mandatory coverage of all or substantially all medications in some of the classes is no longer necessary.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and ACA laws and regulations required that the medications in the 6 protected classes (antidepressant; antipsychotic; anticonvulsant; immunosuppressant; antiretroviral; and antineoplastic agents) remain in place until the Department of Health and Human Services (HHS) establishes additional criteria to identify new categories or classes of clinical concern through notice and comment. MIPPA also provided the Secretary of the Department of HHS with discretion to establish an exceptions process to limit access to certain Part D medications in the protected classes. Since the implementation of MIPPA and ACA, CMS reviewed appropriateness of the coverage parameters in the existing 6 protected classes.
CMS convened a consensus panel that included pharmacists employed by CMS and the Chief Medical Officer for the Center for Medicare to identify the current 6 protected classes to determine appropriateness for the continued coverage parameters. The panel reviewed all of the agents using the American Hospital Formulary Service v6 (AHFS) classification system and found that anticonvulsants, antineoplastics, and antiretroviral classes meet the proposed criteria and thus formularies must continue to cover all or substantially all products in these categories. Conversely CMS’ review found that antidepressant, antipsychotic, and immunosuppressant categories do not meet the new requirements and thus CMS proposes a process allowing regular formulary review of these agents. A clinical analysis of CMS’ findings may be found in the document on page 1944.

If adopted, plans could change formulary management requirements for antidepressants and immunosuppressants in 2015. CMS would provide sub-regulatory guidance on this process at a future date, but seeks comment on whether additional transitional guidance is necessary for antidepressants. CMS will not immediately change the formulary requirement for antipsychotic agents until it determines the appropriate transition process to ensure beneficiary safety. Future changes for classes of clinical concern will likely be provided in the Call Letter or other similar public comment forum.

**CMS’ Rationale for Changes**

After reviewing the medications currently in the 6 protected categories and classes, CMS finds that open access in some categories or classes causes increased drug prices and overutilization for the Medicare Part D program. The policy limits the ability of Part D sponsors to negotiate prices in exchange for formulary placement and limits rebates, a finding backed by a 2011 HHS-OIG report called “Concerns with Rebates in the Medicare Part D Program” (March 2011; OEI-02-08-0050). CMS also cites a 2008 cost analysis study commissioned by AMCP and conducted by Milliman found that the six protected classes disproportionately accounted for 16.8-33.2% of drug spending. Click here to access the report, “Potential Cost Impacts Resulting from CMS Guidance on ‘Special Protections for Six Protected Drug Classifications’ and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275)” CMS also cites other studies with similar findings on page 1937.

CMS notes that plans are not prohibited from negotiating for rebates in these classes, but that such rebates would vary widely and may be minimal, particularly because formulary tier placement has no impact on cost sharing levels for beneficiaries who receive low-income subsidies. As a result, CMS believes that future cost savings could be achieved if plans have more ability to add and remove medications from formularies. The existing coverage policy could also have negative implications on patient safety by limiting the ability of plans to limit coverage to prevent misuse or abuse of medications that are not medically necessary. This may lead to the need for additional unnecessary interventions or lead to patient harm, particularly if the medications are used for off-label indications.

CMS finds that this change could save the Part D approximately $30 million in 2016 and $420 million by 2019 or a total of $720 million over the period 2015-2019.
AMCP Comment Opportunity

- AMCP supports allowing plans to manage medications in all of the existing 6 protected classes.
- Do antidepressants and antipsychotics require additional transition requirements to effectively ensure continued patient safety and quality of care? If yes, what are some examples. If no, why not?
- How may antiretroviral agents and anticancer agents be properly managed to remove them from protected class designation while ensuring appropriate patient access? Is the requirement to include all dosage forms of antiretroviral agents necessary to ensure appropriate patient outcomes?

A. Proposed Expansion of MTM and Reduction in Plan Variability (p 1947)

Upon implementation of the Medicare Part D program, CMS projected that 25% of beneficiaries would qualify for coverage, but actual enrollment has fallen well below that level. Furthermore, CMS suggests that more than 25% of beneficiaries would benefit from MTM. Despite specific requirements that a plan must offer MTM to individuals with a certain number of chronic conditions, and minimum number of Part D covered drugs and spending targets, CMS continues to find restrictive criteria by plans and a lower-than anticipated uptake in MTM.

Past MTM initiatives by CMS encouraged Part D plans to target certain beneficiaries at the beginning of a plan year, but these efforts may not be sufficient to ensure participation in MTM by LIS beneficiaries and other special populations. CMS also finds that if a beneficiary is unable to accept the offer for a comprehensive medication review (CMR), offers to a beneficiary’s prescriber, caregiver, or other authorized individual may not be effectively considered by the sponsor. Furthermore, CMS studies found that certain racial and ethnic disparities continue to exist in meeting MTM criteria and will not decrease without a change in eligibility criteria. CMS cites several research studies on variability in minimum requirements among plans on page 1948 and the impact on update of benefits.

CMS notes that established criteria should be the threshold for MTM eligibility but should not be the driver of interventions by plans. CMS research has found that the best-performing Part D plans improved medication adherence and quality of prescribing while maintaining or reducing overall health care costs despite providing a high number of CMRs. Based on studies conducted by the Center for Medicare and Medicaid Innovation and others, CMS proposes changes to reduce variability in eligibility and improve MTM services and expand access to approximately 55% of beneficiaries by requiring beneficiaries to meet all of the following criteria:

- Reduce the number of multiple chronic diseases eligible for coverage from 4 to 2.
  - One of these chronic diseases must be listed as a core chronic disease as originally defined in 2010 and updated in the 2013 Call Letter. The chronic conditions are:
    - Hypertension;
    - Congestive heart failure;
    - Diabetes;
    - Dyslipidemia;
    - Respiratory disease;
- Bone disease/arthritis;
- Mental health;
- Alzheimer’s disease; and,
- End stage renal disease.

- Beginning in 2015, CMS also proposes to combine hypertension and congestive heart failure under a single term of “cardiovascular disease” which could include: congestive heart failure; heart attacks; cerebral hemorrhage and other effects of strokes; heart arrhythmias; and hypertensive heart disease. CMS might consider further changes in the future and would like comments on the patient populations that should be included in setting those standards.

- Reduce the number of medications required to meet “multiple Part D medications” to 2 or more. Furthermore, CMS will reduce flexibility in by requiring that sponsors consider any Part D covered medications, not just those in certain categories and classes. This change also proposes that beneficiaries who take multiple prescription drugs in conjunction with over-the-counter (OTC) medications are appropriately targeted for MTM and to perform outreach to beneficiaries to learn more about OTC use. CMS solicits comments on alternative definitions for multiple Part D drugs and the minimum number of medications appropriate for targeting. And;

- Proposes lowering the cost threshold from the existing $3,144 to $620. CMS finds that this amount should be reduced based upon the average cost of a 30-day generic prescription at a cost of $25.85. CMS’ cost assumptions show that beneficiaries will fill 2 generic prescriptions per year.

CMS also announced special considerations to enroll certain LIS populations and others who may benefit from MTM but do not meet utilization-based criteria because they are not high utilizers of services. For outreach to these populations, CMS suggests the use of trusted partners, such as pharmacists at the point of sale, increase rates of CMR completion, and dissemination of literature and information in a manner that is sensitive to various populations. CMS proposes that plan sponsors use a unique approach for outreach to special populations and not use a “one-size-fits-all” model. CMS seeks comment on outreach efforts to certain communities. CMS will provide specific outreach to Native American Indians and Alaskan Natives to consider solutions for these populations.

CMS does not have an exact estimate of the costs of the expanded MTM provisions because it is not included as a specific line item in plan bids and therefore cannot be directly extracted. However, CMS estimates that the total costs for providing CMR, including completion and distribution of forms, will be approximately $111 million for all health settings, which is below previous estimates that ranged from $15 million to $143 million. With the implementation of CMR, including data on opt-out rates and beneficiary participation, CMS believes that the current estimate is more accurate.

**AMCP Comment Opportunity**

- AMCP opposes the expansion of the MTM program and opposes legislative and regulatory mandates in the provision medication management services. AMCP is concerned about the proposed expansion because the existing MTM program has not necessarily been effective at reaching the suggested outcomes. AMCP members provide
medication management outside of MTM in a much more effective manner; what examples can AMCP offer to CMS?

- Many Stars Ratings measures are directly linked to or impact to pharmacists’ medication management. Should AMCP consider suggesting to CMS a more direct link between MTM and Star Ratings? What else should AMCP consider?
- How do AMCP members provide outreach to minority and other special populations defined in the rule to improve medication management?

B. Preferred Networks and Preferred Cost Sharing (p 1974)

CMS is concerned that some preferred network cost sharing arrangements might have the effect of increasing subsidized costs from taxpayers because lowered cost sharing results in greater plan costs which are subsidized by government payments. According to CMS, this could occur because preferred networks generally may not impose significantly greater cost sharing for non-preferred network pharmacies because CMS will consider these outliers and thus would be considered discriminatory plans during CMS’ review. As a result, preferred network plans must reduce overall drug plan costs or else the government will pay a greater subsidy to these plans and thus increase the overall cost of the Part D program.

CMS has also found that in some cases, sponsors actually charge greater negotiated prices in preferred networks which also leads to increase costs to the government and taxpayers. This situation also makes beneficiaries make choices that are aligned with plan interests and not the best interest of the Medicare program and the taxpayer because the lower cost sharing is not aligned with the actual negotiated price.

A recent CMS analysis of preferred networks found that outlier excess costs were greater in mail order pharmacies in comparison to retail pharmacies because of increased generic utilization at retail pharmacy. For these reasons, CMS has interpreted any willing pharmacy requirements to require plan sponsors to offer preferred cost sharing for any pharmacy that can offer sufficient discounts to qualify.

Given this data, CMS clarifies that preferred cost sharing should result in consistently lower costs to beneficiaries and the government. The proposed definition would require preferred networks to offer reduced copayments or coinsurance as long as preferred cost sharing is offered in accordance with Part D any willing pharmacy standard and the Part D drug costs must have significantly lower negotiated prices than the same drugs obtained in the rest of the network. This means that plans must offer beneficiaries and the Part D program lower negotiated on all drugs in return for lower cost sharing. This could then result in deeper reimbursement discounts for preferred drugs. CMS believes this is reasonable because it finds that mail order pharmacies have significantly more leverage with manufacturers and wholesalers than smaller pharmacies.

CMS seeks comments on other ways to use negotiated price to allow for preferred networks to operate without increasing overall costs and government payments. CMS also seeks comment on whether standards should be established to determine how low drug costs should be in return for preferred cost sharing. CMS seeks input on either Medicare should require a minimum level of savings, such as 10-15% over the costs available at retail cost-sharing rates. CMS’ analysis shows that based on 2013 preferred network prices, these discounts must be substantial. CMS also seeks comments how broadly preferred cost sharing should be applied to drugs on a
formulary. CMS believes that if rules are not in place to require plans to offer all drugs at preferred rates, beneficiaries may pay more for certain drugs at the preferred pharmacy for convenience purposes and the Part D program also pays additional costs.

CMS also proposes that it eliminate the term “preferred networks” and rather use “preferred cost sharing.” CMS believes that this will eliminate the connotation that some network pharmacies are considered “non-preferred pharmacies” without the opportunity to meet the terms and conditions to qualify for preferred cost sharing. CMS also finds this term misleading because not all medications are offered at decreased cost sharing at preferred network pharmacies, some may be limited only to generics or other preferred tier products. Preferred cost sharing would mean lower cost sharing for certain Part D drugs offered in network pharmacies. CMS would also require revisions to marketing materials to reflect the updated terminology and remove references to preferred networks. CMS emphasizes that plans would not be required to offer preferred cost sharing.

**AMCP Comment Opportunity**

- AMCP supports the use of preferred networks as a managed care tool to allow beneficiaries to receive affordable access to medications.
- Define the “pros” and “cons” of preferred cost sharing versus preferred networks. How would this change impact the ability to offer competitive and reduced costs for medications in the market place?
- How could the use of preferred-cost sharing rather than preferred networks impact future networks that could be based upon performance metrics rather than solely on dispensing services?

**D. Any Willing Pharmacy Terms and Conditions (p 1978)**

CMS proposes that plans offer a single contract with standard terms for any willing pharmacy that includes all potential preferred cost combinations and negotiated prices possible for retail settings. This would be a new alternative to current market practice where plans offer different contracts for preferred and non-preferred pharmacies.

The contracts should contain the floor and ceiling prices for lower and upper limits on preferred contract pricing. Negotiated prices charged by pharmacies with preferred cost sharing must be at or below the agreed ceiling price. Based on CMS analysis of 2012 claims, CMS finds that preferred networks do not always result in consistent savings across medication classes and that some non-preferred pharmacies may offer better rates than network pharmacies. CMS’ proposed solution is to expand networks consistent with preferred cost sharing rather than continue with the preferred pharmacy structure.

CMS believes a change will level the playing field for small independent community pharmacies to participate in preferred cost sharing in networks that do not offer any willing pharmacy the opportunity. Further, if some retail pharmacies were able to offer deeper discounts than sponsors are currently negotiating with pharmacies in return for preferred cost sharing, competition will be increased and aggregate negotiated prices will be reduced.
CMS’ new proposed definition of any willing pharmacy includes the following key points:

- Increased access for beneficiaries to preferred level cost share with any willing pharmacy able to agree to the terms and conditions that include preferred cost sharing.
- Improved opportunity for competition among pharmacies contracting with the sponsor to charge no more than the ceiling price stated in the contract for preferred cost sharing.
- Improved clarity for beneficiaries about cost sharing levels at mail order and retail pharmacies.

The revised contract structure that provides the terms and conditions for both preferred and non-preferred cost sharing would permit retail pharmacies to choose one or the other or both. Preferred cost sharing would allow sponsors to limit pharmacies to those that accept the stated ceiling prices in the terms and conditions. All pharmacies, including those “related” to the Part D sponsor or its PBM, would have to offer prices below the ceiling negotiated prices and contracts would be prohibited for preferred cost sharing with higher negotiated prices. Public pricing standards would then set a pricing floor for all pharmacies accepting a plans standard terms and conditions.

CMS clarifies that the terms and conditions for network pharmacies may differ among contracts for different types of pharmacy, including retail, mail order, long-term care (LTC), limited distribution or specialty, and home infusion. CMS recognizes that beneficiaries in LTC, specialty, and home infusion do not always seek preferred cost sharing nor would it necessarily be efficient to offer preferred pricing in these networks. CMS proposes to limit cost sharing in these pharmacies to the standard monthly rate as is the practice today. Any pharmacy engaged in less than 30 day dispensing will continue to be subject to the daily cost sharing requirements.

E. Mail Order Pharmacy (p 1980)

Proposed Fulfillment Requirements
CMS is concerned that beneficiaries who choose mail order pharmacy may experience unnecessary and extended delays in receiving prescriptions because they must wait between 7-10 days for a regular delivery but if problems occur, then this waiting time could be extended. CMS contrasts this to the experience in the community pharmacy setting where a prescription is presented and filled on the same day and any problems with the prescription are resolved in real time. CMS is concerned that extended waiting times for access to mail order medications may result in gaps in therapy. As a result, CMS proposes to establish required contractual fulfillment requirements for prescriptions received from mail order pharmacies. CMS finds that the proposed fulfillment requirements are “consistent with mail order fulfillment lines in other markets” and are as follows:

- Prescriptions with issues such illegible orders, resolving third party rejection, and coordination of utilization management must be shipped within 5 days of receipt; and
- Prescriptions without issues must be shipped within 3 days.

CMS acknowledges that many of the proposed requirements are already met by “established companies that have been providing these services for years” and that the number of prescriptions received via mail order continues to represent a relatively small percentage of total prescriptions. Therefore, CMS does not believe these present an undue burden or create a new
standard but solicits input on the time frame and other circumstances where a 5-day time frame would apply.

CMS also seeks comments on whether it should create additional requirements for beneficiary materials related to mail order services using the following areas as examples:

- Definitions of processing and delivery time;
- Process for accessing customer support;
- Process to submit a complaint to 1 800 MEDICARE;
- Beneficiary options for accessing medications when a delivery is lost or delayed; and
- Resolving inappropriate or inapplicable edits, such as refill too soon.

Extended Days’ Supply at Retail and Mail Order Pharmacies (p 1980)
CMS will continue to allow differing cost sharing levels to be offered for extended days’ supply, generally greater than 34 and but no more than 102 at both retail and mail order pharmacies. To avoid confusion, CMS indicates that plans should use a maximum of two cost sharing distinctions based on days’ supply: a one month supply not to exceed 34 days or an extended days’ supply of greater than 34 days. Sponsors must make available to any willing retail pharmacies an extended supply addendum to existing terms and conditions. The addendum would allow the same cost sharing rate as mail order if a retail pharmacy meets the terms and conditions or be offered at another higher cost-sharing level, but not higher than 3 times the amount the enrollee would have paid at the same retail pharmacy for a 1-month supply at the same cost sharing rate. The days’ supply pricing differential would not apply to LTC, specialty, and infusion because these businesses generally do not operate on days’ supply.

Mail Order Cost Sharing and Use of Mail Order for 1 Month Supplies
Mail order cost sharing for an extended days’ supply may be less than the preferred cost sharing amount for an extended days’ supply filled at retail. For 1 month supplies, CMS proposes that the cost sharing may not be less than the standard cost sharing at retail for a 34 days’ supply or less regardless of whether a preferred cost sharing level is available.

CMS finds that mail order prescription fulfillment for initial fills or routine 30-day supplies are not good practices. It indicates that it has received complaints that the relatively short time necessary to fill 30-day supplies is not sufficient to ensure that delivery is made in a timely manner, particularly when problems occur and retail pharmacies must be used in the interim. While CMS does not seek to present a disincentive against this practice and does not propose any rules to stop this practice, it seeks comment on the use of mail order for prescriptions one month or less.

F. Formal Interpretation of Non-Interference Previsions (p 1969)
CMS believes that given the number of inquiries it receives, it must formally interpret the boundaries of the Medicare Modernization Act’s (MMA) non-interference provisions. The non-interference clause prohibits CMS interference in negotiations between and among pharmaceutical manufacturers, pharmacies, and prescription drug program (PDP) sponsors and may not specify a specific formulary or Part D price structure. CMS interprets the two goals in the following way:
CMS should promote private market competition in Part D drug formulary selection by plan sponsors.

CMS should not create any policies that would be expected to interfere with competitive market negotiations leading to drug product selection.

CMS further describes its role in administering Part D and states it is to decrease transaction costs of acquisition information on products offered in the market; increase price transparency; ensuring a large number of buyers and sellers; and minimize market entry barriers to the extent possible while ensuring quality. CMS will continue its practice to allow plan autonomy on medication product selection and formulary creation and management. CMS will also not interfere in negotiations between pharmaceutical companies and pharmacies for medication purchases. CMS has also indicated that it will not be involved in application of any pricing benchmarks used to determine pharmaceutical purchase price or reimbursement, but it may establish definitions of the scope of a consistent standard. However, CMS finds that it has a different role between plan sponsors and pharmacies. CMS finds several statutory provisions that require general CMS oversight and therefore this is consistent with congressional intent to explain oversight and compliance with CMS requirements. CMS declines to become a direct party to contracts or arbiter of the meaning of contracts.

CMS cites the following provisions as being consistent with congressional intent where CMS has general oversight in providing guidance on CMS requirements:

- Interpretation of the definition of access to negotiated prices;
- Any willing pharmacy standard terms and conditions
- Prohibition on any requirement to accept insurance risk
- Prompt payment,
- Payment standard update requirements;
- Disclosure of drug costs in the marketplace
- Projected Part D bid amounts that are publicly available.

G. Prescription Drug Pricing Standards and Maximum Allowable Cost (MAC) (p 2040)

CMS proposes an updated definition of “prescription drug pricing standard” for purposes of reporting Medicare Part D drug prices to CMS to include MAC prices and other formulas that rely on varying prices and not a fixed, published price. This change is the result of complaints by pharmacies to CMS about inconsistency and uncertainty surrounding MAC pricing. Thus, even though MAC is not based upon a published price, CMS supports plan reporting allow pharmacies to have current data on the amount of reimbursement expected.

CMS is also concerned that MAC prices not based published drug pricing standard presents risks to the Medicare Part D program in a number of ways. Accurate pricing information is necessary for pharmacies to ensure accurate payment of claims and is necessary for cost accuracy in submitting claims to CMS on prescription drug event (PDE) files without unnecessary later adjustments that could disrupt Part D operations. Without accurate, current pricing data, CMS believes that information in the Medicare Part D plan finder tool is also questionable and does not allow beneficiaries to make good drug purchasing choices.
The proposal would also require sponsors to agree in contracts with CMS to disclose all individual drug prices and provide updates to applicable pharmacies in advance of reimbursement of claims if the source for any prescription drug pricing standard is not publicly available. This, then, would require that Part D sponsors to convey MAC pricing changes to network pharmacies in advance of such as change.

**AMCP Comment Opportunity**

- How could this change impact the ability to provide cost effective generics in the market?

**H. Cost Sharing for Transition Supplies (p 2039)**

To eliminate confusion that CMS finds occurs in some situations associated with transition fills and to prevent beneficiaries from unnecessarily paying higher cost-sharing or co-payments during or after the transition period, CMS proposes the following cost-sharing methodology:

- LIS beneficiaries must not be charged a higher cost-sharing for transition supplies than the statutory maximum co-payment amounts.
- Non-LIS beneficiaries must be charged the same cost sharing for non-formulary Part D medications provided during the transition that would apply to 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.

**I. Pharmacy Price Concessions in Negotiated Price (p 2039)**

CMS proposes to include some pharmacy price concessions in the determination of negotiated price. CMS finds that these concessions are often excluded because they are often characterized as network access fees; administrative fees; technical fees; or service fees that are not defined explicitly in contracts. Pharmacies contend that these fees do not provide any value, but rather are applied to transaction fees for claims’ submission, help desk support, health information technology issues, and other expenses associated with credentialing maintaining, and auditing pharmacy networks. CMS finds that these fees are deductions in payments to pharmacies for drugs dispensed, but represent charges that offset operated expenses from the sponsor or pharmacy benefit management (PBM) company. If the sponsor seeks compensation for these services, then these costs should be accounted for in the Part D bid. If the sponsor deducts these costs from pharmacy payments for purchases of Part D drugs, these would be considered price concessions and incorporated into Part D cost reporting.

CMS would require that the dispensing fees could only be applied at the point of sale if they are received and retained by the pharmacy in the negotiated price. Most commenters to CMS on this issue in the past, including PBMs, sponsors, and pharmacies, have noted that these fees are price concessions and therefore, must be reported as administrative costs. Incentive payments to pharmacies, such as generic dispensing fees because these payments represent an amount the sponsor bears to encourage efficient drug choices and therefore will not be considered price concessions. These payments could be reported later as negative direct and indirect remuneration.
CMS further finds that risk sharing arrangements or conditional payments based on volume are not compatible with the point of sale price competition envisioned by the statute. It notes that these arrangements could overstate the negotiated prices at point of sale, and require subsequent adjustments through direct and indirect reporting that may increase beneficiary and government costs if specific targets are met.

CMS’ new proposed definition of negotiated price:

- The amount that the Part D sponsor (or other intermediary) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount a network entity will receive, in total for a particular drug; and,
- Are inclusive of all price concessions and any other fees charged to network pharmacies; and,
- Includes any dispensing fees; but
- Exclude additional contingent amounts, such as incentive fees, only if these amounts increase prices and cannot be predicted in advance; and,
- May not be rebated back to the Part D sponsor (or other intermediary contacting organization.)

J. Payments to PDP Sponsors for Qualified Prescription Drug Coverage (p 1974)

CMS proposes an update to the definition of prices “actually paid” to include references to incentive payments, and to clarify that direct and indirect remuneration may include additional payments to pharmacies, such as incentive payments, but may not include any other price concessions from pharmacies because these must be in the form of negotiated prices.

CMS proposes to eliminate coupons from the list of price concessions because these do not impact prices paid to a pharmacy on a claim. Furthermore, knowing and willful use of coupons to reduce cost-sharing obligations of federal health program beneficiaries is prohibited by the anti-kickback statute and therefore, Medicare Part D eligible individuals may not use them.

K. Fraud, Waste, and Abuse, Audit, and Compliance Provisions (various pages, see specific sections below)

Allowance for CMS to Levy Civil Monetary Penalties (CMPs) for Some Violations (p 1925)

The proposal seeks to allow CMS to impose CMPs for certain Medicare Part D infractions, including violations of the marketing rule and engaging in business with entities or individuals subject to exclusion from federal health care programs. Currently, only the Department of Health and Human Services Office of Inspector General (HHS-OIG) is permitted to impose CMPs for these violations. The proposed rule would allow either CMS or HHS-OIG to impose penalties. HHS-OIG would continue to have sole authority to impose CMPs for penalties related to misrepresentation or falsification of information presented to CMS or another entity.

Proposal to Require “CMS Standardized General Compliance Program Training and Education Module” for use by All Part C and D Plans (p 1926)

CMS proposes this training module to assist Medicare Part C and D plans train first downstream and related entities (FDRs), including pharmacies and physicians, using a single, general compliance program. Until this proposed rule, this module was considered optional, but now
CMS proposes to require all organizations to accept a certificate of completion of this training program as the only sufficient method to satisfy the training requirement. CMS believes that this would eliminate the need for multiple training programs for FDRs. Plan sponsors would be permitted to provide a 1-page supplementary information sheet to provide in conjunction with the CMS training materials. CMS proposes that this information either be provided by the sponsor in the contract or could be distributed separately by the contractor to FDRs. CMS seeks comment on this proposal and suggestions for other options that may be implemented.

Proposed Changes to CMS Audit Inspection Requirements for Part C and D Plans (p 1927)
Pursuant to provisions in the Affordable Care Act (ACA), CMS proposes that contracted plans provide the right to timely access to audit inspections of records, facilities, protections against certain financial losses or services performed under the contract.

Part C and D plans would also be required to hire an independent authority to perform full or partial CMS program audits. CMS notes that it does not have the capacity to audit all of its 300 partner organizations with Medicare Advantage or Medicare Part D contracts and thus the requirement for hiring an independent contractor would “benefit” organizations and enrolled beneficiaries to ensure quality services. All audit protocols are available to sponsors on the CMS website. If the proposal is adopted, plan sponsors selected for audit must hire an independent auditor to conduct the audit on behalf of CMS either every 3 years or if specifically selected for an audit. CMS will issue further sub-regulatory guidance related to provision of audit agreements between the sponsoring organization and independent auditor. CMS will continue to perform audits in limited scenarios, such as when indicated by a risk analysis or “look back” audits to ensure independence of the auditor. If non-compliance is found, CMS proposes that plan sponsors hire an independent auditor to validate that a correction has occurred.

CMS describes the criteria for organizations chosen for audits, including at least one of the following:
- High star rated plans;
- Sponsors that have received a Low Performing Icon (LPI);
- High risk plans based on data-driven assessments
- Sponsors not audited in the last 3 years; and
- Referrals from CMS regional or central office.

Prior to an audit, CMS conducts a risk assessment to determine organizations at high-risk with contract performance or data indicators that demonstrate the potential risk of failing to perform program functions that may result in beneficiary harm.

CMS estimates that this change would require an annual cost of $7.95 million or a total of $39.75 over the period 2015-2019 for all auditing organizations to perform the audit. Part D plan sponsors would likely spend $950,000 annually or $4.75 million in years 2015-2019 to implement these programs.

Experience Requirements for Plan Sponsors or FDRs (p 1958)
To ensure that Medicare operations run as smoothly as possible and that beneficiaries may be serviced at a consistent level, CMS will require that a plan sponsor or an FDR providing services
must have prior experience, within the past 2 years for at least 1 full year in Part D at the time of
the application in the following areas:

- Authorization, adjudication, and pharmacy claims processing at the point of sale;
- Administration and tracking of enrollees’ drug benefit in real time, including automated
  coordination of benefits; and
- Operation of enrollee appeals and grievance processes.

Authority to Directly Request Information from FDRs (p 1955)

HHS, Comptroller General, or designees would have the right to obtain records to audit,
evaluate, collect, and inspect any records from FDRs, including PBMs, pharmacies, and
physicians. CMS finds that this requirement would reduce the burden on plan sponsors to obtain
this information on behalf of CMS. Plan sponsors would receive notification from CMS when it
conducts inspections for FDRs. This proposal does not consider whether CMS has authority to
enter the premises of FDRs which will be resolved by interpretations of other laws and
regulations.

Implementing Affordable Care Act Provisions Requiring Reporting and Return of Overpayments
(p 1995)
The ACA requires that any person receiving an overpayment from a federal health care program
to report and return the overpayment to HHS, the state, or any other applicable intermediary or
contractor and notify HHS in writing of the overpayment return with a rationale. Payments must
be returned within 60 days after the overpayment was identified or the due date of the
corresponding cost report. CMS proposes rules to implement the provisions of the ACA for Part
D sponsors and Medicare Advantage Program with prescription drug benefits (MA-PDs).

Use of Recovery Audit Contractors (RACs) and Proposed Appeals Process for Part C and D
Plans (p 2005)
The ACA includes provisions to expand the use of RACs for the Part D program. RACs are
auditors charged with identifying improper Medicare claims and recouping inappropriate
payments or overpayments or reimburse underpayments to plans. CMS contracted with the first
Part D RAC in January 2011. The first Part C RAC will be announced in 2014. CMS proposes a
process for Part C and D plans to appeal RAC determinations. Appeals may be sought for a
determination of any monetary value. The appeals would include an independent validation of
whether payment was improper followed by a notice to the plan. Following the determination of
an overpayment, a demand letter would be sent seeking the reason for the overpayment
determination; explain the recoupment process; and instruct plans on the appeals process.

The appeals process allows for reconsiderations within 60 days of demand letter for
circumstances when CMS payment methodology is improperly applied (this does not allow for
appeals related to the substantive basis of CMS’ payment methodology). CMS then has 30 days
to rebut the independent reviewer’s determination. Reconsideration determinations would be
final and binding unless the plan requests a hearing within 15 days of a determination. If a plan is
not satisfied with the hearing decision, then a CMS Administrator review request may be filed
within 15 days. If the Administrator declines the request, the hearing decision is final. If the
Administrator reviews the request, then CMS would file a rebuttal statement within 30 days of
the Administrator’s notice to the plan. The Administrator would then send written notice of its determination to the plan and that decision is final.

L. Managing Disclosure and Recusal in Pharmacy and Therapeutics Committee (P&T) Conflicts of Interest (CoI) for Formulary Development under Part D (p 2019)

CMS proposes a requirement that P&T committees establish minimum standards and policies and procedures for determining whether disclosed financial interests are CoI and to manage recusals because of conflicts of interest. The determination of whether a CoI exists and management of recusals must be made by an objective party.

AMCP Comment Opportunity

- Is a CMS requirement necessary to prevent CoI in Part D P&T Committees? Why or why not?

M. Enrollment Requirements for Part D Covered Drug Prescribers (p 1982)

Consistent with requirements implemented by the ACA, beginning January 1, 2015, CMS proposes that a prescriber must:

- Be enrolled pursuant to an approved enrollment record in the Medicare fee for service (FFS) program (CMS seeks comment on whether this requirement should also include doctors of dental medicine or surgery) or
- Have a valid opt-out affidavit on file with a Part A/B Medicare Administrative Contractor (MAC). (The MACs then verify each applicants Social Security number and National Provider Identifier number at the time of enrollment, when changes or updates are submitted; verifies state licensing board information prior to enrolling the practitioner and then monthly thereafter; and, ensures that prescribers have not been excluded from federal health program participation.)

CMS also proposes the following requirements to prescribe for Medicare Part D covered drugs:

- Deny eligibility if the Drug Enforcement Certificate for prescribing is currently suspended or revoked; or
- The applicable licensing or administrative body in the state which the prescriber practices has suspended or revoked licensure and such suspension or revocation is in effect the date he or she submits enrollment and the suspension or revocation is effective the date of submission of the enrollment application to the Medicare contractor.

- CMS also proposes that it may revoke an eligible professional’s Medicare enrollment if a prescriber shows 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.
  - CMS has chosen not to specifically define the exact elements of abusive practices and the exact practices that represent a threat to the health and safety of Medicare beneficiaries because of the “myriad of questionable situations that warrant the possible application of this section…that CMS should have the flexibility to address each case on its own merits”. However, CMS will consider the following factors:
- Whether a diagnosis exists to support the indication;
- Whether a patient evaluation did not occur;
- Whether the prescriber has been involved in prescribing excessive dosages of controlled substances linked to patient overdoses;
- Number and type of disciplinary action against prescriber by state(s);
- Whether the prescriber has any history of “final adverse actions”;
- Number and type of malpractice suits filed against prescriber that have resulted in a final judgment and a settlement paid to a plaintiff;
- Restriction, suspensions, termination of prescribing rights by Medicaid or other private health insurance program; and,
- Any other relevant information provided to CMS.

To determine whether a prescriber has a pattern of practice that fails to meet Medicare requirements, CMS will consider the following factors:
- Pattern of prescribing without valid authority;
- Pattern of prescribing outside of the scope of DEA Certificate of Registration;
- Has a pattern of prescribing outside of FDA approved indicators or other medically accepted uses, including peer reviewed literature or community standards, and whether the prescriber acted in reckless disregard for patient health and safety.

CMS seeks general comments on the proposed criteria and any additional criteria should be used.

CMS is also seeking comment on whether network pharmacies should also be required to be enrolled in the Medicare FFS program to leverage credentialing, identity verification, and other safeguards as part of the enrollment process. CMS seeks comment on whether required Medicare FFS enrollment is a best practice and should be a part of a sponsor's required fraud, waste, and abuse programs. CMS also seeks comment on whether it should consider some or all of the proposed criteria for excluding prescribers from Medicare Part D to pharmacies.

**AMCP Comment Opportunity**

- Should prescribers be required to enroll in the Medicare FFS program? Why or why not? If not, what other criteria should be used to guard against prescribers who are not properly certified?
- Are the suggested requirements for exclusion appropriate or too extensive? Are there any others that should be considered?
- Should pharmacies be required to register with the Medicare FFS program?

**N. Proposal to Expand Release of PDE Data (p 1988)**

CMS believes that to facilitate better health outcomes and promote health care data sharing, it needs to expand its policy for release of PDE data related to unencrypted prescriber, pharmacy, and plan identifiers to all current categories of requestors (including other HHS entities, Congressional oversight agencies, non-executive HHS branch agencies and states, and external entities.) Increased access to data could facilitate research by entities outside CMS while continuing to maintain beneficiary confidentiality and commercially sensitive data by ensuring release of only the minimum necessary. This data sharing would exclude bids, rebates, and other price concessions outside of the scope of the PDE data release policies. Furthermore, information
related to separate costs paid by Part D sponsors for ingredient costs or dispensing fees would remain confidential and only be released in encrypted form to outside entities. This information would remain available in disaggregated form only to other HHS entities and congressional oversight agencies. CMS would exclude sales tax upon, except upon request, at the individual level, if necessary for the project.

CMS does not believe that unnecessary conflicts of interest or the potential for undue pharmaceutical manufacturer influence would arise by releasing unencrypted information about prescribers because the prescriptions written should be appropriate for patient care and thus have no privacy concerns. In addition, new provisions known as the “Sunshine Act” passed under the ACA require prescribers to report certain payments or other remuneration annually to HHS and federal Anti-kickback laws also apply in these situations. CMS also notes that prescriber data are available from commercially available data aggregators and therefore, the release of unencrypted PDE information is not much different from current industry practice.

Other solicitation for comments on release of PDE data:

- Should CMS continue the current prohibition on release of PDE information to commercial entities? CMS seeks comment but does not offer a formal proposal.
- Proposes to add support of state program integrity programs as a necessary and appropriate release of PDE data.
- Clarifies that non-final action data, such as information on claims subject to subsequent adjustment are available to entities outside of CMS. This PDE field distinguishes original from adjusted or deleted PDE records.

**AMCP Comment Opportunity**

- Should CMS release unencrypted PDE information to qualified entities? If not, then why should this data remain encrypted?
- How would release of unencrypted PDE information advance research?
- What protections are necessary to ensure that the data are properly secured?

**O. Addition of Contractual Terms for Part C and D Plans to Demonstrate the Provision of Good Quality Health Care (p 2007)**

CMS proposes to require contract language explicitly requiring the Part C and D plans to demonstrate the provision of good quality health care by achieving good or improving scores on CMS performance standards for outcomes, intermediate outcomes, process, patient experience, and access to patient care. CMS proposes to utilize the link between the objective quality metrics framework, i.e. the Stars Program, to define the subjective term “good quality health care.” Good quality health care relates to the performance measures in the five categories identified in the CMS Stars Ratings Program:

- Patient outcomes;
- Intermediate outcomes;
- Patient experience;
- Patient access to care; and,
- Process.
CMS believes that linking the five categories to the provision of good quality health care provides an opportunity to demonstrate value offered to enrollees while providing a means to enforce corrective action when a plan fails to meet the standards. CMS’ proposes standards would enact in regulation contract terms that plans must demonstrate Star Ratings or performance standards of a score of 3 or higher.

**P. Clarification of Definition of Part D Drugs (p 2020)**

*Combination Products*
CMS proposes that only combination drugs approved by the Food and Drug Administration, including vaccines, insulin, or biologics, may be eligible for Part D coverage. Combination products, including convenience packaging with multiple products in a single box and single agent products with multiple active ingredients, and vitamins, where at least one of the products is not approved by the FDA would not be eligible for Part D coverage.

*Barbiturates and Benzodiazepines*
Under provisions of the ACA, beginning January 1, 2014, barbiturates are considered eligible for coverage under Part D for any indication. This rule codifies these requirements. (In 2013, Part D barbiturate coverage was limited to uses in epilepsy, cancer, or a chronic mental health disorder and prior to that were excluded from Medicare Part D coverage.)

*Medical Foods*
CMS proposes adding medical foods to the list of excluded Part D products. This exclusion would not impact Part D coverage for parenteral nutrition.

*Clarification of Coverage for Compounded Products*
CMS does not propose changes to the rules for coverage of compounded products. CMS clarifies that compounded products containing ingredients that independently meet the definition of a Part D drug would be covered. However, products are compounded or packaged in convenience packaging for broad distribution would not meet the definition of a Part D drug.

**Q. MA-PD Coordination Requirements for Drugs Covered under Parts A, B, and D (p 2008)**

CMS proposes a regulation that MA-PD plans must establish adequate messaging and processing requirements with network pharmacies to ensure that appropriate payment is assigned at the point of sale. PDPs must ensure that when Part D coverage is denied because of available Part A or B coverage, the coverage is authorized or provided as expeditiously as the enrollee’s health condition requires. CMS clarifies that this provision would not require all authorizations at the point of sale because doing so must result in retrospective liability or other issues to the enrollee and the plan. CMS would also require MA-PDs to receive the appropriate authorizations and not require beneficiaries to seek authorization. CMS seeks comment on these provisions and the best practices that MA-PD plans utilize to make coverage determinations at the point of sale.
R. Clarification of 3-year Coordination of Benefits Timeframe (p 2021)

CMS proposes to clarify that the timeframe for coordination of benefits by Part D sponsors with state pharmaceutical assistance programs and other secondary payers is 3 years from the date the prescription for a covered Part D drug was filled. Existing regulations include the phrase “for a period not to exceed 3 years,” which according to CMS, has created confusion among plans that the timeframe could be less than 3 years.

S. Application and Calculation of Daily Cost Sharing Rates (p 2022)

Effective January 1, 2014, plans must impose daily cost sharing rates for medications dispensed in less than monthly increments, unless a regulatory exemption applies. CMS does not provide oversight on the manner of negotiating, calculating, or paying dispensing fees, but has provided guidance on how to sponsors may implement a daily cost sharing rate. To reduce confusion regarding the definition of a “month’s supply”, CMS proposes that plans have the ability to establish the definition of a month’s supply. CMS has previously used 30 or 31 days to define a month’s supply which presented problems for some plans that do not apply the same number of days. The cost sharing or co-insurance amount must be calculated using the actual days dispensed.

CMS also proposes to clarify existing language related to rounding by indicating that plans may round the daily cost sharing rate to the nearest cent. CMS clarifies that rounding the daily cost sharing rate may not result in beneficiaries paying more than the approved monthly co-payment amount. CMS would allow the beneficiary to pay a “nominally greater than approved cost sharing” for the first incremental fill for beneficiaries who are synchronizing medications, which only occurs infrequently and in most cases one time.

T. Changes to Short-Cycle Dispensing for Long-Term Care Facilities (LTCFs) (p 1964)

CMS proposes the following changes to the requirement that pharmacies providing services to LTCFs dispense brand name oral solid medications in quantities of 14 days or less:

- Sponsors may not prohibit payment arrangements that promote the adoption of more efficient LTC dispensing techniques. This provision would prohibit prorated LTC dispensing fee because CMS’ analysis finds that the cost of dispensing is not directly related to the quantity dispensed.
- Eliminates language that has been misinterpreted as requiring prorated dispensing fees.
- Provides a waiver for LTC pharmacy systems that use dispensing systems that reduce waste and where medications may be safely returned to stock and reused. This does not require plans to credit the dispensing fee back. CMS seeks comments on ways to implement this waive, qualifications for the waiver, and if any medications exist that should not be restocked.
- Eliminates the requirement that sponsors report on the nature and quantity of unused brand and generic drugs.

If you have questions regarding this summary, please contact Mary Jo Carden, AMCP’s Director of Regulatory Affairs by phone at 703-683-8416 ext 603 or by email: mcarden@amcp.org.