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AMCP Focus Areas: CMS 2015 Medicare Part D Proposed Rule

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Comments due: March 7, 2014

In January, AMCP provided you with an extensive summary, shortly after the Centers for Medicare and Medicaid Services (CMS) released a Medicare Part D proposed rule called the 2015 Medicare Part D proposed rule (42 CFR Parts 409, 417, 422, 423, and 424). 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 AMCP summary provides an overview of the specific areas where AMCP will comment to CMS. **AMCP would like your feedback on the focus areas of the proposed rule. AMCP needs data and information to bolster the comment document.** AMCP has also prepared a Powerpoint presentation with an overview of the comment areas. **To provide comments, please email mcarden@amcp.org by 5 pm EST on Thursday, February 27, 2014.**

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.

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 page1944.

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 p 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 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?

- 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?

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 approprate 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.. 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?

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.

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 wiling 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?

Any Willing Pharmacy Terms and Conditions (p 1978)

CMS proposes that plans offer a single contract with standard terms for any wiling 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.

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.

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 to 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.

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.