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SUMMARY

AMCP Summary: ***Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program***

Released: ***November 16, 2017***

Comments Due: ***January 16, 2018***

On November 16th, the Centers for Medicare and Medicaid Services (CMS) released a much anticipated proposed rule titled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program." The proposed rule amends regulations for Medicare Part C and Medicare Part D to implement provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act. The proposed rule also makes changes to improve program quality, accessibility, and affordability and also adopts the updated NCPDP script standard for electronic prescribing. CMS estimates that the proposed rule has a net savings of $80 to $100 million for each of the next five years.

The 713-page proposed rule is very robust and includes several major policy provisions that impact managed care pharmacy, both positively and negatively. AMCP previously provided detailed comments to CMS on how the Medicare Part C and D programs can be transformed through innovation to best meet the individual health needs of Medicare beneficiaries. AMCP is pleased to see that the proposed rule incorporates several of the recommendations put forth by AMCP including:

- Categorization of biosimilars as applicable drugs under Medicare Part D;
- Increased flexibility to implement midyear formulary changes;
- Revisions to the MLR calculation to include in the MLR numerator expenditures related to fraud reduction activities (including fraud prevention, fraud detection, and fraud recovery) and Medication Therapy Management (MTM) programs;
- Adoption of the revised NCPDP SCRIPT standard for e-prescribing; and
- Electronic delivery of certain required notifications.

However, there are also several provisions in the proposed rule that AMCP is concerned about and is seeking stakeholder feedback on.

Comments on this proposal must be submitted to CMS by January 16, 2018 at 5:00PM EST. AMCP will work with stakeholders to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced as changes to the Medicare Part C and D program are considered. You may provide feedback via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Friday, January 5, 2018 on any of the provisions included in the proposed rule. AMCP's final comments to CMS will be available on the AMCP website and also included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

In addition, AMCP will host a webinar on Wednesday, December 6, 2017 from 2:00 – 3:00PM EST to review the provisions of the proposed rule that are applicable to managed care pharmacy and seek stakeholder feedback to inform AMCP's

comments to CMS. This webinar is free for members and $69 for non-members. Registration will be available after November 20, 2017 at http://amcp.org/calendar/.

The following are areas of specific importance to AMCP that it is seeking feedback on from stakeholders:

- Drug Management Programs:
  - Is integrating the drug management provisions of CARA with the current DUR and OMS policy appropriate? Should the drug management provisions be considered separate and independent from DUR and OMS? What are the implications to this integration in caring for at-risk beneficiaries?
  - Should the list of frequently abused drugs include benzodiazepines, muscle relaxants, or other non-opioid controlled substances?
  - Is adoption of the 2018 OMS criteria as the clinical guidelines for use in drug management programs sufficient?
  - Can sponsor's systems account for all prescribers within a group practice as a single prescriber or chain pharmacies as a single pharmacy when determining at-risk beneficiaries – is this approach feasible?
  - Should sponsors should have flexibility in developing their own criteria for identifying at-risk beneficiaries in their plans, or is a more uniform approach specified by CMS preferred?
  - Exempting cancer patients from drug management programs was not specified in CARA but is being proposed by CMS – is this an appropriate exemption? Are there other types of patients that should also be exempted, such as patients at the end-of-life?
  - Are the case management requirements proposed by CMS too burdensome?
  - Is prescriber agreement necessary? Should sponsors have the ability to enroll a beneficiary in a drug management program even if the prescriber does not agree?
  - Is the timeline for providing a second notice appropriate, should it be shortened or lengthened?
  - Should additional exemptions to the 30 day timeline between the initial and secondary notice be recognized by CMS, such as in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court?
  - Is the 6 month waiting period for limiting an at-risk beneficiary to a selected prescriber reasonable – should it be shortened or lengthened?
  - Is using the existing Part D benefits appeals process for drug management program appropriate?
  - Is the 12-month maximum enrollment in a drug management program sufficient – should it be shortened or lengthened?
  - Are there other considerations for the implementation of drug management programs in Medicare Part D that CMS should consider?
- Tiering Exceptions:
  - How will CMS' interpretation of "lowest applicable cost sharing tier" impact sponsors? Does the interpretation interfere with sponsor's ability to manage formulary design?
- Quality Rating System:
  - What are additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans?
  - How can CMS' current process for establishing the cut points for Star Rating be simplified? Do the relative performance as reflected by the existing cut points accurately reflects plan quality?
  - How should CMS should measure overall improvement across the Star Ratings measures?

- Should CMS consider additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance?
- Should the weight of patient experience/complaints and access measures be increased? If yes, what should the weight be increased to?

- Any Willing Provider:
  - What are the implications of expanding the definition of retail pharmacy to include a "walk-in" requirement? How will this impact pharmacy networks?
  - Do the proposed definitions of "retail pharmacy" and "mail-order pharmacy" strike the right balance to resolve confusion in the marketplace, afford sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models?
  - Should sponsors be allowed to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies?
  - Should sponsors be allowed to develop sponsor or PBM specific credentialing criteria for network pharmacies in lieu of accreditation standards?
  - Are the proposed deadlines for sponsors to furnish their standard terms and conditions to requesting pharmacies operationally realistic? Are longer timeframes needed?
- Manufacturer Rebates and Pharmacy Concessions:
  - How would a point-of-sale rebate policy impact sponsors and premiums?
  - Would adoption of a point-of-sale rebate policy make the Part D market more competitive and efficient?

Detailed information on each of the key AMCP issues contained in the proposed rule is outlined in the summary below.

Implementation of the CARA Provisions - Medicare Part D Drug Management Programs (pages 27 - 105)

The Comprehensive Addiction and Recovery Act of 2016 (CARA) included provisions that permitted Part D sponsors to utilize drug management programs, commonly referred to as lock-in programs, to limit beneficiaries at-risk for substance abuse to a single prescriber and/or pharmacy. A detailed summary of CARA and its provisions is available here. AMCP also previously provided detailed comments to CMS regarding implementation of the drug management provisions of CARA. In the proposed rule, CMS details how it intends to implement the drug management provisions of CARA and seeks feedback on its approach and current thinking.

CMS proposes to implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS), which would be codified. By integrating the programs, a sponsor could limit a beneficiaries' access to coverage for such drugs through pharmacy lock-in, prescriber lock-in, and/or a beneficiary-specific point-of-sale (POS) claim edit after case management and notice to the beneficiary. To do so, the beneficiary would have to meet clinical guidelines that factor in that the beneficiary is taking a high-risk dose of opioids over a sustained time period and that the beneficiary is obtaining them from multiple prescribers and multiple pharmacies. CMS proposes to exempt beneficiaries with cancer, in hospice, or in long-term care from drug management programs. Sponsors would report to CMS the status and results of their case management to OMS and any beneficiary coverage limitations they have implemented to MARx, CMS' system for payment and enrollment transactions.

CMS also proposes implementing a limitation on the use of the special enrollment period (SEP) for low income subsidy (LIS)-eligible beneficiaries who are identified as potential at-risk beneficiaries.

Frequently abused drugs → For 2019, CMS proposes to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables (due to low claim volume and inability to determine MME). CMS specifically notes that it is not compelled to include benzodiazepines, muscle relaxants, or other non-opioid controlled substances at this time, but seeks feedback on this approach. CMS proposes to update the list of frequently abused drugs annually via the Call Letter process.

Clinical guidelines → For 2019, CMS proposes the clinical guidelines for use in drug management programs should be the OMS criteria established for plan year 2018. Specifically: use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies OR 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. Under the proposal, sponsors would not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs, except sponsors will continue to be permitted to apply the criteria more frequently than CMS would apply them (e.g. CMS evaluates every six months whereas a sponsor may evaluate monthly). CMS notes that while several commenters stated that Part D plan sponsors should have flexibility in developing their own criteria for identifying at-risk beneficiaries in their plans, CMS believes a more conservative and uniform approach is warranted for the initial implementation of Part D drug management programs.

CMS also notes that in applying the clinical guidelines, prescribers within a group practice or chain pharmacies would be considered a single prescriber and/or a single pharmacy for the purposes of the clinical guidelines. CMS is seeking feedback on whether sponsor's systems can account for prescribers within a group practice or chain pharmacies as a single entity and the feasibility of this approach.

Policies & procedures → CMS proposes to require sponsors document their programs in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. The policies and procedures should also address the appropriate credentials of the personnel conducting case management and the necessary and appropriate contents of files for case management. Sponsors would also be required to monitor information about incoming enrollees who meet the definition of a potential at-risk and an at-risk beneficiary and respond to requests from other sponsors for information about potential at-risk and at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans within 14 days of receiving a request.

Case management → To meet the requirements of case management, CMS proposes that a sponsor must do all of the following: (A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at-risk beneficiary; (B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary; and (C) In cases where the prescribers have not responded to the inquiry described in (i)(B) , make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information. CMS proposes that an exemption to the case management requirement would be if the beneficiary was already identified as meeting the clinical guidelines by their most recent prior plan so long as the sponsor obtains case management information from the previous sponsor and such information is still clinically adequate and up to date.

Prescriber verification and agreement → CMS proposes that in addition to case management, a sponsor must first obtain the agreement of the prescribers of frequently abused drugs to enter the beneficiary into a drug management program, unless the prescribers were not responsive to the required case management. It is unclear whether a sponsor can continue with enrolling a beneficiary in a drug management program if the prescribers do not agree.

Initial notice to beneficiary → CMS proposes that the initial notice must use language approved by the Secretary and be in a readable and understandable format. CMS proposes that the initial notice include two additional elements that are otherwise not required under CARA: 1) information about public health resources that are designed to address prescription drug abuse; and 2) the limitation the sponsors intends to place on the beneficiary's access to coverage for frequently abused drugs, the timeframe for the sponsor's decision, and, if applicable, any limitation on the availability of the SEP. CMS also proposes that beneficiaries be given 30 days to provide additional information to the sponsor that is relevant to the determination. CMS also proposes that the sponsor be required to make reasonable efforts to provide the prescriber(s) of frequently abused drugs with a copy of the notice. CMS also proposes that the initial notice will notify dually- and other low income subsidy (LIS)-eligible beneficiaries, that they will be unable to use the special enrollment period (SEP) for LIS beneficiaries due to their at-risk status.

Second notice to beneficiary → CMS proposes to require the sponsor to provide the second notice when it determines that the beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs. The second notice should include the effective and end date of the limitation. Like the initial notice, the second notice should use language approved by the Secretary and be in a readable and understandable format and a reasonable effort should be made to provide the prescriber(s) of frequently abused drugs a copy of the notice. CMS also proposes that if a sponsor does not implement the limitation on the potential at-risk beneficiary's access to coverage of frequently abused drugs it described in the initial notice, then the sponsor would be required to provide the beneficiary with an alternate second notice. CMS proposes that the second notice should be issued on a date that is not less than 30 days and not more than 90 days after the date of the initial notice. CMS notes that a second notice may be sent immediately to a beneficiary who was identified as at-risk by their prior plan and received an initial notice from their prior plan. CMS notes that in their current thinking, exemptions to the 30 day timeline between the initial and second notice may not be otherwise waived, even in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court.

Limiting access to a selected prescriber → CMS proposes that a sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary.

Beneficiary preferences → CMS proposes that in addition to the beneficiary preference provisions contained in CARA for selecting a prescriber or pharmacy, the selected prescriber or pharmacy must be in-network. An exception is if the beneficiary is a member of a PDP and requires a selected physician as PDPs do not have physician networks and the plan sponsor must generally select the prescriber that the beneficiary prefers, unless an exception applies. CMS proposes that the sponsor must inform the beneficiary of the selection in the second notice, or if not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission. CMS also proposes that if the sponsor determines that the beneficiary preference would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy or beneficiary and if the sponsor provides the beneficiary with at least 30 days advance written notice of the change and a rationale for the change.

CMS notes that it is not limiting the number of times a beneficiary can submit their preferences, but it seeking comment on whether a limit should be created. Furthermore, CMS proposes that if a beneficiary does not submit their preferences, that the sponsor may make the selection on the beneficiary's behalf as long as reasonable access is accounted for.

Confirmation of prescriber or pharmacy selection → CMS proposes that a sponsor may obtain a network provider's confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries' selected prescriber or pharmacy, as applicable.

Appeals → CMS proposes that appeals for drug management programs follow the existing Part D benefits appeals process. Consistent with existing rules for redeterminations, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the second written notice to make such request, unless the enrollee shows good cause for untimely filing. CMS also proposed that at-risk beneficiaries must affirmatively request IRE review of adverse plan level appeal decisions made under a plan sponsor's drug management program. In other words, proposal, an adverse redetermination would not be automatically escalated to the Part D IRE, unless the plan sponsor fails to meet the redetermination adjudication timeframe.

Termination → CMS proposes a maximum 12-month period for drug management programs. Therefore, a beneficiary should be terminated from a drug management program the sooner of the 12-month maximum period or once they demonstrate that they are no longer at-risk. CMS notes that there are no restrictions on a sponsor re-identifying a beneficiary as at-risk post-termination as new information is available to the sponsor.

Data sharing → CMS proposes that sponsors must do all of the following: (A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS; (B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries; (C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs; and (D) Transfer case management information upon request of a gaining sponsor as soon as possible but no later than 2 weeks from the gaining sponsor's request when: (1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and (2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

Part D Tiering Exceptions (pages 148 – 158)

CMS proposes to make regulatory changes to prohibit sponsors from excluding non-preferred generic-drug tiers from tiering exceptions. CMS notes that as the price of drugs has grown, formularies have gotten more complex, leading to expanded tiers that in some cases mix brands and generics, and multiple tiers for generic drugs. CMS proposes to base eligibility for tiering exceptions on the tier that contains the preferred alternative drug to the higher-cost requested drug, rather than based on tier labels established by the plan. This would remove an existing loophole whereby plans could exclude generic tiers, including non-preferred generic tiers, from the tiering exception system. Specialty tiers will still be excluded from the exception system.

> AMCP Comments: AMCP does not support CMS' interpretation of "applicable lower cost-sharing tier" and believes it undermines the development of evidence-based formularies which enhance the quality of patient care by

selecting the most appropriate medications for patients with the goals of reducing treatment failures, adverse drug events and hospitalizations and improving patient adherence and health outcomes.

Quality Rating System (pages 168 – 262)

CMS proposes to codify key aspects of the Part C and D Star Ratings methodology, including the principles for adding, updating, and retiring measures (aka the Call Letter process), and the methodology for calculating and weighting measures. CMS proposes codifying this process to demonstrate a commitment to transparency and predictability for the future. CMS also proposes:

- New rules related to how contract consolidations affect stars to more accurately reflect performance of the surviving and consumed contracts, and
- New methods for applying scaled reductions when CMS determines that the data for the appeals measures is not complete to allow for smaller reductions for less serious data issues. These changes will support CMS' efforts to improve the quality of care for Medicare beneficiaries.

CMS also requests feedback on several elements of the Quality Rating System including:

- Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.
- Whether CMS' current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality.
- How CMS should measure overall improvement across the Star Ratings measures.
- Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance.

Any Willing Provider Standards (pages 262 – 278)

CMS clarifies that although sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, sponsors may not exclude pharmacies with unique or innovative business or care delivery models (e.g. compounding pharmacies, specialty pharmacies, retail pharmacies that also operates a home infusion line of business, etc.) from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. In particular, CMS considers "similarly situated" pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.

CMS proposes to define "mail-order pharmacy" as "a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing." CMS proposes to define mail-order pharmacy to clarify that a retail pharmacy who has a line of business that offers home delivery should not be classified as a mail-order pharmacy by sponsors.

CMS also proposes to redefine "retail pharmacy" to mean "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy." The

primary change here is the addition of the concept of "walk-in" which would expand how the definition of retail pharmacy has historically been interpreted to include all community and independent based pharmacies that are open to the general public.

CMS declines to propose a definition for "specialty pharmacy" as the landscape for specialty drugs continues to evolve and they believe any attempt to define it would be premature and inappropriately interfere with the marketplace. CMS also declines to propose a definition for "non-retail pharmacy."

CMS also notes that it does not support the use of sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations. CMS also notes that it would not expect sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so.

CMS also proposes to establish deadlines by which sponsors must furnish their standard terms and conditions to requesting pharmacies to minimize delays in pharmacies entering a sponsor's network under the any willing provider provisions. CMS proposes the following deadlines:

- Sponsors must have standard terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year
- Sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request
    - In instances where the sponsor requires a pharmacy to execute a confidentiality agreement with respect to the terms and conditions, the Part D plan sponsor would be required to provide the confidentiality agreement within two business days after receipt of the pharmacy's request and then provide the standard terms and conditions within two business days after receipt of the signed confidentiality agreement

Changes to the Days' Supply Required by the Part D Transition Process (pages 278 – 282)

CMS proposes to change the transition supply requirements for long-term care patients from 91 – 98 days to 30 days due to concerns with waste and costs. CMS also makes a minor adjustment and clarifies the transition supply requirements for outpatient is one month and not necessarily 30 days to account for medications that are packaged as 28 day supplies.

Midyear Formulary Changes (pages 282 – 296)

CMS proposes to provide sponsors with more flexibility to implement generic substitutions and not require a 60 day notice period or preclude sponsors from making a change within the first two months of a plan year. CMS proposes to permit sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met. The generic drug would need to be offered at the same or a lower cost-sharing and with the same or less restrictive utilization management criteria originally applied to the brand name drug. The sponsor could not have as a matter of timing been able to previously request CMS approval of the change because the generic drug had not yet been released to the market. Also, the sponsor must have previously provided prospective and current enrollees general notice that certain generic substitutions could occur without additional advance notice. As proposed, CMS would permit sponsors to substitute a generic drug for a brand

name drug immediately rather than make that change effective, for instance, at the start of the next month. CMS also clarifies that this provision would not apply to biosimilars that are not considered interchangeable by the FDA.

CMS also proposes reducing the 60 day advanced notice period for 30 days. A sponsor would need to provide at least 30 days' online notice to affected enrollees before removing drugs or making cost-sharing changes except when adding a therapeutically equivalent generic or removing unsafe or withdrawn drugs. This change would allow sponsors to implement midyear formulary changes in a more expedited manner.

AMCP Comments: AMCP supports increased flexibility for sponsors to implement midyear formulary changes.

Biosimilars (pages 296 – 300)

CMS proposes to revise the definition of generic drug at § 423.4 to include follow-on biological products approved under section 351(k) pathway. CMS proposes this change to lower cost sharing for lower cost alternatives and improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and reduce costs to both Part D enrollees and the Part D program. CMS notes that its classification of follow-on biologics as generic drugs is only for the purpose of non-LIS catastrophic cost sharing and LIS cost sharing and is not to be universally applied across all CMS policy.

AMCP Comments: AMCP supports the classification of biosimilars as applicable drugs under Medicare Part D.

Meaningful Differences Requirement (pages 300 – 305)

CMS proposes to eliminate an artificial limit (called the "meaningful difference" requirement) on Enhanced Alternative (EA) benefit designs offered by the same organization in the same region. CMS is not changing this requirement as it applies between Basic and EA prescription drug plan offerings

Manufacturer Rebates and Price Concessions (pages 306 – 339)

The proposed rule includes a Request for Information (RFI) soliciting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale. CMS intends to review the ideas and comments provided in response to the RFI to evaluate and consider proposals for rulemaking. However, CMS notes that it is unclear whether they have the authority to make such changes. CMS also notes that a point-of-sale rebate policy would likely increase premiums -- and therefore Medicare's direct subsidies of plan premiums and low-income premium subsidies -- but overall out-of-pocket costs would likely be lower for beneficiaries.

Revisions to Timing and Method of Disclosure Requirements (pages 350 – 357)

CMS proposes to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC) to alleviate plan burden related to printing and mailing, an estimated savings to plans of $55 million in 2019. CMS also proposes to change the timeframe for delivery of the EOC to the first day of the Annual Election Period (AEP) rather than fifteen days prior to that date to separate it from delivery of the Annual Notice of Change (ANOC).

AMCP Comments: AMCP supports the electronic delivery of documents required under Medicare as it alleviates plan burden, decreases administrative costs on the healthcare system, and also reduces the number of paper documents that beneficiaries receive from plans.

Part D Payment Redeterminations and IRE Reconsiderations (pages 372 – 374)

CMS proposes to lengthen existing timeframes for adjudicating enrollee payment appeal requests at the redetermination and independent review entity (IRE) reconsideration levels from a maximum of 7 calendar days to a maximum of 14 calendar days. This change would reduce burden on sponsors and the Part D IRE by providing them additional time to adjudicate payment requests with little adverse impact on beneficiaries, who in payment appeals have already obtained the requested medications.

Updating the Part D E-Prescribing Standards (pages 376 – 384)

CMS proposes to adopt the NDPDP SCRIPT Standard Version 2017071, and retire the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

AMCP Comments: AMCP supports adoption of the updated NCPDP SCRIPT standard for e-prescribing. However, CMS' proposal does not require use of the NCPDP electronic prior authorization (ePA) standard. AMCP supports the adoption of the ePA standard approved by NCPDP to improve efficiencies in the prior authorization process and improve patient outcomes. In comments, AMCP will encourage CMS to reconsider requiring use of the NCPDP ePA standard to help reduce POS rejections and improve the Medicare Part D member experience.

Part D Preclusion Lists for Physicians and Eligible Professionals (pages 386 – 411)

CMS proposes to rescind the current provisions in § 423.120(c)(6) that require physicians and eligible professionals to enroll in or validly opt-out of Medicare in order for a Part D drug prescribed by the physician or eligible professional to be covered. As a replacement, CMS proposes that a Part D plan sponsor must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the "preclusion list," which would be defined in § 423.100 and would consist of certain prescribers who are currently revoked from the Medicare program under §424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. However, CMS also proposes that in order to ensure continuity in therapy for beneficiaries, plan sponsors may not reject claims or deny beneficiary requests for reimbursement for a drug on the basis of the prescriber's inclusion on the preclusion list unless the sponsor has first covered a 90-day provisional supply of the drug and provide individualized written notice to the beneficiary that the drug is being covered on a provisional basis.

Medical Loss Ratio Requirements (pages 446 – 459)

CMS proposes certain changes to the treatment of expenses for fraud reduction activities in the Medicare MLR calculation. First, CMS proposes to revise the MA and Part D regulations by removing the current exclusion of fraud prevention activities from Quality Improving Activities (QIA). Second, CMS proposes to expand the definition of

QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. Third, CMS proposes to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses. CMS notes that commercial MLR rules and the Medicaid MLR rules are outside the scope of this proposed rule.

CMS also proposes that that all Medication Therapy Management (MTM) programs that comply with § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans) are QIA and therefore will be included in the MLR calculation.

> AMCP Comments: AMCP strongly supports the inclusion of fraud prevention expenditures in incurred claims for MLR reporting purposes. AMCP believes that including fraud, waste, and abuse expenses in the MLR calculation, rather than treating them as administrative costs, would encourage health plans to field more robust fraud detection programs and avoid efforts to pare back those activities.
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> AMCP strongly supports the inclusion of MTM programs in the medical loss ratio (MLR) as quality improving activities. AMCP believes the inclusion of MTM programs in the MLR as a quality improving activity would further encourage and incentivize providers to strengthen their MTM programs, resulting in increased healthcare outcomes and decreased healthcare costs.