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***Submitted electronically via* www.regulations.gov**

January 16, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: 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.

Dear Administrator Verma:

CVS Health appreciates the opportunity to comment on the Calendar Year (CY) 2019 Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule and Request for Information (RFI) published in the *Federal Register*, vol. 82, no. 227 (November 28, 2017).

CVS Health is a pharmacy innovation company helping people on their path to better health. Caremark, our PBM company, covers 11.6 million Medicare Part D beneficiaries, and SilverScript, our national Medicare Part D plan, covers almost 6 million beneficiaries. Through our more than 7,900 retail drugstores, more than 1,000 walk-in medical clinics, a leading pharmacy benefits manager (PBM) with more than 70 million plan members, a dedicated senior pharmacy care business serving more than one million patients per year, and expanding specialty pharmacy services, we enable people, businesses, and communities to manage health in more affordable, effective ways. Our unique integrated model increases access to quality care, delivers better health outcomes, and lowers overall health care costs.

CVS Health appreciates the opportunity to provide comments on the proposed rule and RFI. If you have any questions or require additional information, please contact Donald Dempsey, Vice President, Policy and Regulatory Affairs at donald.dempsey@cvshealth.com or (202) 772-3534.

Sincerely,

Don Dempsey
Vice President
Policy and Regulatory Affairs

Enclosures: 2019 Proposed Rule Comments

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CVSHealth

2019 Proposed Rule

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions.

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c. Integration of CARA and the Current Part D Opioid DUR Policy and OMS

We support the integration of the prescriber and pharmacy lock provisions of Comprehensive Addiction and Recovery Act (CARA) with the existing Part D opioid drug utilization review (DUR) policies and the Overutilization Monitoring System (OMS). We did not note any features of the existing Opioid DUR guidance that were not addressed in this proposed rule.

(i) Definitions

(B) Definition of "Frequently Abused Drug", "Clinical Guidelines", “Program Size”, and "Exempted Beneficiary" (§423.100)

Frequently Abused Drugs:

We are concerned with the Centers for Medicare & Medicaid (CMS) limiting the "frequently abused drugs" definition to only opioids for plan year 2019. While we appreciate CMS wanting to gain experience with the new prescriber and pharmacy lock provisions, most plans have been utilizing prescriber and pharmacy lock in their Medicaid and Commercial lines of business for many years. Limiting the reviews to only opioids for both the OMS beneficiary-specific POS edits as well as the lock-ins limits the plan's ability to manage all potentially abused or misused controlled substances. While opioids are the focus of many national initiatives, we believe that it is important to review and manage all of the controlled substances a beneficiary may be taking in order to reduce risk of significant adverse events.

The Drug Enforcement Agency (DEA) defines schedule II controlled substances as drugs with "a high potential for abuse which may lead to severe psychological or physical dependence." Schedule II drugs include opioids, stimulants and some additional drugs. The DEA defines Schedule III controlled substances as those with "a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence." Schedule III drugs include opioids and anabolic steroids. Schedule IV is defined as drugs with "a low potential for abuse relative to substances in schedule III." Schedule IV includes benzodiazepines, tramadol, and carisoprodol. We believe any controlled substance in Schedules II-IV has the potential to be a "frequently abused drug." More importantly, many beneficiaries are taking Schedule II opioids with Schedule IV benzodiazepines - a combination known to increase the risk of death from an overdose.

The Centers for Disease Control and Prevention (CDC) opioid guidelines note the added risk of the combination of opioids and benzodiazepines. Our experience with our retrospective controlled substance overutilization program has been that beneficiaries at-risk for adverse events often take multiple controlled substances, including opioids, benzodiazepines and pregabalin. Our experience has shown that approximately 20-25% of the beneficiary-specific POS edits that we have implemented for opioids include limitations on non-opioid controlled substances, including benzodiazepines, as well. In addition, approximately 50% of cases reviewed in March 2017 for potential opioid overutilization included benzodiazepines. We currently include these non-opioid controlled substances in our overutilization interventions. Concern about the use of multiple controlled substances, specifically the combination of opioids and benzodiazepines, is further evidenced by the addition of the concurrent opioid-benzodiazepine flag in the quarterly OMS reports. In the HPMS memo titled, "Medicare Part D Overutilization Monitoring System (OMS) Update: Addition of the Concurrent Opioid-Benzodiazepine Use Flag," issued October 16, 2016, CMS noted, "CMS' expectation is that Part D sponsors will consider benzodiazepine use within their opioid overutilization review process and include this information within their discussions with prescriber(s)."

Recommendation: We strongly encourage CMS to define Frequently Abused Drugs as any controlled substance (DEA Schedule II-IV), and continue to allow plans the flexibility to implement beneficiary-specific POS edits on all drugs deemed necessary by the plan in consultation with the beneficiary's prescriber. Plans currently can and do intervene on these cases of multiple controlled substance overutilization, including implementing beneficiary-specific POS edits, and we feel it is important that plans can continue to use this tool. Furthermore, we recommend that prescriber and pharmacy locks be permitted for any controlled substance, as appropriate.

Clinical Guidelines and Program Size:

While we support the use of the 2018 OMS opioid targeting for 2019, we request that CMS continue to allow plans to have flexibility in their targeting criteria. Plans may use additional targeting criteria to identify potentially at-risk individuals that are not necessarily based on the OMS criteria, but are consistent with the CDC guidelines. For example, a beneficiary that has filled opioid prescriptions from 10 different prescribers in the last 6 months, but who has an average MME of < 90 mg/day, would benefit from better coordination of care that could be achieved using a pharmacy or prescriber lock. These individuals would not be identified by CMS as part of the OMS.

Recommendation: CMS should allow plans to continue to utilize additional targeting criteria to identify potentially at-risk beneficiaries. Plans should be allowed to implement beneficiary-specific POS edits and locks for beneficiaries who demonstrate prescriber or pharmacy shopping behavior, but stay below the average morphine milligram equivalent (MME) of 90 mg/day, or are on combinations of controlled substances that place the beneficiary at risk for an adverse event.

Exempted Beneficiary:

We support exempting beneficiaries who have elected hospice and those residing in long-term care facilities from the OMS interventions and prescriber/pharmacy lock. While we agree that individuals being treated for cancer-related pain should also be exempt from these limitations, we do not believe a cancer diagnosis, in and of itself, should be an exemption. There are many people who have a cancer diagnosis in their history who may be taking opioids for pain unrelated to their cancer diagnosis. For instance, a woman who was successfully treated for skin cancer 5 years ago, with no sign of recurrence, may be at-risk for opioid overutilization due to pain subsequent to a motor vehicle accident 2 years ago.

Recommendation: Beneficiaries in hospice or residing in long-term care should be exempt from the OMS opioid limitations. Beneficiaries currently being treated for cancer-related pain should also be exempt. However, a history of cancer, in and of itself, should not be sufficient to exempt an individual from the OMS limitations. CMS should permit plans to exempt beneficiaries with cancer-related pain from opioid limitations *after* consultation with the prescriber. Plans should not be prohibited from reviewing potential at-risk beneficiaries for opioid management because they are not identified on the OMS report because of a history of cancer.

(v) Limitations on Access to Coverage for Frequently Abused Drugs

We would like for CMS to clarify that a beneficiary could have any combination of a beneficiary-specific POS edit, prescriber and/or pharmacy lock, and that these limitations do not have to be implemented at the same time. For example, a pharmacy lock is implemented for a beneficiary with a history of provider shopping. Six months later, the beneficiary is still showing excessive use of controlled substances (e.g., fewer prescribers, but higher quantities) and his/her primary prescriber has requested that a beneficiary-specific POS edit be added to the pharmacy lock to better manage the controlled substances.

(vi) Requirements for Limiting Access to Coverage for Frequently Abused Drugs

We agree that the plan should get prescriber agreement for any beneficiary-specific POS edits or prescriber lock for at-risk beneficiaries, unless the prescriber(s) is unresponsive. However, we do not support obtaining prescriber agreement for a pharmacy lock. Pharmacy lock is primarily used when the beneficiary has shown a clear pattern of provider shopping, including primarily utilizing emergency departments to obtain controlled substance prescriptions. This behavior indicates a lack of care coordination. It could be extremely difficult for the plan to gain agreement from all controlled substance prescribers, or even identify who would be the primary provider to implement the pharmacy lock.

(vii) Beneficiary Notices and Limitation of Special Enrollment Period

(A) Initial Notice to Beneficiary and Sponsor Intent to Implement Limitation on Access to Coverage for Frequently Abused Drugs.

It is our understanding from this NPRM that CMS will be providing model letters for the first and second beneficiary notifications. We request that CMS clearly identifies areas of variable text vs required text. Will plans be able to modify these letters (other than the variable fields)? Plans will need at least four months to implement and fully test beneficiary letters. A longer lead-in time would be needed if plans need to get these letters approved by CMS.

CMS proposes to require the initial notification to include "public health resources designed to address prescription drug abuse." Please confirm that CMS will be including this information in the model letter. A standalone Part D Plan sponsor would not know what resources a beneficiary would have available from their health plan. If each health plan must include the resources specific to their plan, PBMs that are delegated these letters by plan sponsors would need additional time to program plan-specific language. This would increase the time to implement letters to at least 6 months and will add new costs to the implementation of the letters.

(B) Limitation on the Special Enrollment Period for LIS Beneficiaries with an At-Risk Status.

We support limiting the special enrollment period (SEP) for dual eligible and low income subsidy beneficiaries that have a controlled substance limitation in place. CMS will need to provide plans with specific transactional data in a timely manner when the at-risk beneficiary is prohibited from changing plans, as well as when the beneficiary qualifies for an SEP while they do not have an active limitation in place.
We also support limiting the SEP for other dual eligible and low income subsidy beneficiaries to one election per plan year.

(C) Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs.

Again, it is our understanding from the NPRM that CMS will be providing model letters for the first and second beneficiary notifications. All comments associated with the initial letter would also apply to the second notice.

(D) Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur.

The most likely scenario where a limitation would not be implemented after the initial notice would be if the beneficiary or prescriber successfully appealed the restriction. Since CMS has indicated that these appeals would follow the same process as a redetermination, please confirm that the redetermination approval letter would be sufficient notification that the limitation will not occur, and that a separate letter would not be needed. CMS could provide language to be used in the redetermination approval letter that meets the intent of the alternate second notice.

(E) Timing of Notices.

We understand that CMS will require the second notice to be sent to the at-risk beneficiary not less than 30 days after the initial notice, and that the second notice must include the effective date of the limitation. How long must the plan wait between the second notice and the effective date? Would this be an additional 30 days from the date of the second notice, or can the plan implement the limitation sooner (e.g., 14 days)? If the plan must wait 30 days after the second notice to implement the limitation, it will have been at least 60 days since the beneficiary was determined to be at-risk before any limitations can be initiated. Also, in the case of a prescriber or pharmacy lock, if the beneficiary provides his/her preferences and they are acceptable, must the plan still wait 30 days before sending the second notice?

Recommendation: For lock-in limitations, the plan should be able to implement the lock within 30 days of the initial notification if the beneficiary provides his/her prescriber or pharmacy preferences. If the preferences are not provided within 30 days, the lock-in limitations should be able to be implemented within 14 days of the second notice. If the beneficiary changes his/her preferences, the new lock-in preferences are effective 14 days after the plan receives them. For beneficiary-specific POS edits, where prescriber and/or pharmacy preferences are not required, the limitation should be effective 30 days after the initial notification. The second notification serves as a courtesy reminder.

(A) Special Requirement to Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s).

We do not agree with requiring a plan to wait at least six months from the time a beneficiary was identified as being potentially at-risk before being allowed to pursue a prescriber lock if warranted. As described earlier, if a beneficiary is provider shopping, the beneficiary may not be exceeding the average MME per day, but clearly needs better care coordination. We request that plans have the flexibility to implement prescriber lock sooner than 6 months for the following reasons:

- If the overutilization continues to be egregious,
- If the prescriber requests the lock, or
- If helping the beneficiary obtain better coordination of care through a prescriber lock is an appropriate course of action.

(B) Selection of Pharmacies and Prescribers.

We agree with the guidelines for honoring the beneficiary's preference for prescriber and/or pharmacy in a lock limitation. However, we do not agree that the beneficiary should be allowed to change their preferences as often as they wish. In an earlier section of the NPRM, CMS closed the SEP loophole that allowed beneficiaries to avoid a limitation by changing plans. By allowing beneficiaries to make unlimited changes to their prescriber or pharmacy preferences, it will again be possible to avoid the implementation of the limitation by simply requesting a

different prescriber or pharmacy. How long must the plan wait after the beneficiary has requested a change in prescriber or pharmacy before the plan can implement the limitation?

Recommendation: Beneficiaries should not be permitted to change their preferences more than two times in a plan year, unless they can provide good cause for requesting the change. Examples of good cause would include moving beyond easy access to the prescriber or pharmacy; the prescriber has discharged the beneficiary from his/her practice; or the pharmacy is unable to provide the requested drugs. Plans should be able to implement the limitation 14 days after a change has been requested.

CARA states that for the purpose of limiting access to a specific pharmacy(s), if the pharmacy has multiple locations that share real-time electronic data, all such locations should be treated collectively as one pharmacy. We support the concept of treating a pharmacy with multiple locations as a single pharmacy if they share real-time data; however, the plan may not always know which pharmacies have this connectivity. In addition, some pharmacy chains have been known to limit shared data by geographic region. If a beneficiary is locked into a pharmacy chain, one cannot assume that all locations will have visibility to all claims.

Recommendation: We ask that CMS allow plans some flexibility when locking beneficiaries into a pharmacy with multiple locations - especially if the plan is unable to verify that all locations share real-time data. In this circumstance, the plan may need to limit the member to a specific pharmacy or a specific region.

Regarding the proposed requirement to treat all providers in a group practice as a single provider for a lock-in limitation, plans and PBMs do not have the ability to identify all practitioners in the same practice in real-time at point-of-service, especially as group practices add practitioners or practitioners change location. The prescriber's tax identification number (TIN) is not part of the claim transaction data. The plan would have to get agreement from each provider to participate in the lock, and set up the lock for multiple providers.

Recommendation: Plans should not be required to treat all prescribers in the same practice as a single prescriber at POS for the purposes of a prescriber lock. Plans should be able to provide reject overrides when it is determined that the prescriber is in the same practice as the locked-in prescriber.

(ix) Drug Management Program Appeals.

Please confirm that when a beneficiary "appeals" their controlled substance limitation, that the request should be processed as a redetermination and not a coverage determination. Also please confirm whether or not the beneficiary should be provided with CMS-10147 - Prescription Drug Coverage and Your Rights, if they have a claim reject due to a controlled substance limitation.

Appeal requests for opioid/controlled substance limitations under CARA do not currently fit any Part D utilization management criteria (e.g., exception criteria are not really appropriate in this circumstance. If a beneficiary appeals the limitation beyond the plan (i.e., Independent Review

Entity, Administrative Law Judge, etc.), will these higher appeal authorities know to evaluate these appeals based on the at-risk determination of the plan and not based on exception criteria?

There may be instances where a beneficiary needs a temporary change in his/her opioid/controlled substance limitation. For example, the beneficiary may be undergoing a surgical procedure that requires a temporary increase in the amount of opioids allowed under a beneficiary-specific POS edit. Per Chapter 18, exception requests must be approved through the end of the plan year. This may not be appropriate for a beneficiary at-risk for substance use disorder. Will CMS allow plans to implement temporary exceptions to limitations that are not through the end of the plan year if done so in consultation with the beneficiary's prescriber?

Recommendation: We do not recommend providing beneficiaries with CMS-10147 when a claim rejects due to a beneficiary-specific POS edit, prescriber or pharmacy lock. This form could cause confusion as it refers to a coverage determination and lists the turnaround times for a coverage determination, rather than for a redetermination. We recommend that CMS provide additional guidance to plans and higher appeal authorities on how to assess appeals for opioid/controlled substance limitations initiated under the CARA rules, and how to differentiate these appeals from other coverage determination appeals. We also recommend that CMS provide guidance to allow plans to temporarily change a limitation for a specific timeframe without requiring the plan to approve the exception through the end of the plan year.

(x) Termination of a Beneficiary's Potential At-Risk or At-Risk Status.

CMS has proposed a 12-month duration limit on beneficiary-specific POS edits and prescriber/pharmacy locks. We do not feel that a 12 month limit is appropriate as these limits were implemented because other interventions were not effective. The beneficiary and prescriber can appeal the limitations at any time, which would allow for changes in therapy, or discontinuation of a lock/beneficiary-specific POS edit. If the limitation must be terminated at the end of 12 months, how long must the plan wait to reinstitute the limit if appropriate? Must the plan send both the initial and second notice to reinstitute the limits?

Recommendation: Require the plan to reassess the limits every 12 months to ascertain whether the beneficiary is still taking the controlled substances and to reconfirm with the prescriber that the limits are appropriate. As noted above, the beneficiary or prescriber can request the limits be lifted at any time (appeal). If the plan must terminate the limit after 12 months, allow the plan to reinstate the limits as soon as it notes at-risk behavior without waiting for the beneficiary to be identified in the OMS report. Allow the plan to reinstate the limits utilizing only the second notice in order to prevent unsafe utilization.

(xi) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments.

We agree with using the same data disclosure and information sharing processes that are in place for the OMS. Please confirm that CMS will be providing new response codes for prescriber and pharmacy locks. Since CMS is going to require plans to review all cases identified in the OMS report, the OMS response code of BSC (Beneficiary did not meet the sponsor's internal criteria) would no longer be valid. Please confirm whether or not plans should continue to submit

Sponsor-Identified Potential Overutilization Issues (SPIs) cases that they identified using their own criteria and were not identified on the OMS report. This would include those instances of provider shopping where the beneficiary was getting prescriptions from multiple prescribers, but did not exceed the average MME per day.

Recommendation: CMS will provide new response codes for prescriber and pharmacy locks for the OMS reporting. CMS should continue to allow plans to implement and submit SPI cases to CMS that did not meet (or did not meet yet) the CMS targeting criteria.

9. Part D Tiering Exceptions

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We would like to commend CMS for updating the regulations on tiering exceptions by taking into consideration how plan formularies have evolved over the last several years. We would like CMS to confirm our understanding of the new regulations regarding tiering exceptions.

1. Drugs on the specialty tier continue to be exempt from tiering exceptions.
2. Brand drugs must be approved to the lowest cost-share that contains a brand drug used to treat the same condition. That lowest cost-share may be the specialty tier.
3. Biologic products, not on the specialty tier, must be approved to the lowest cost-share for biologics used to treat the same condition. The lowest cost-share may be the specialty tier.
4. Generic drugs must be approved to the lowest cost-share that contains a generic drug, including authorized generics, used to treat the same condition.

We would like CMS to confirm our understanding of the new rules for tiering exception requests for generic drugs. In the NPRM, there are three different descriptions of the rules for tiering exceptions for generic drugs:

> "…plans would be required to approve tiering exceptions for non-preferred generic drugs when the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives."
>
> "Similarly, tiering exceptions for non-preferred generic drugs would be assigned to the lowest applicable cost-sharing associated with alternatives that are either brand or generic drugs (see further discussion later in this section related to assignment of cost-sharing for approved tiering exceptions to the lowest applicable tier)."
>
> "Plans would be required to grant a tiering exception for a higher cost generic or authorized generic drug to the cost sharing associated with the lowest tier containing generic and/or authorized generic alternatives when the medical necessity criteria is met."

Please confirm that CMS's intent is that generic drugs, including authorized generics, must be approved to the lowest cost-sharing that applies to a generic or authorized generic used to treat the same condition. The lowest cost-sharing could be a tier that contains both brands and generics or it could be a tier that contains only generics and authorized generics.

Please confirm that the CMS definition of a biologic is a drug that was approved via a Biologics License Application (BLA).

We commend CMS for providing a definition of generic drugs and authorized generic drugs. We would encourage CMS to expand this exception to further allow the inclusion of other drugs the plan considers to be comparable to generics. For example, Levoxyl (levothyroxine, NDA #021301) is commonly included on generic tiers. It carries a generic Multi-Source Code in Medi-Span and may be substituted for other brand name levothyroxine products such as Synthroid. However, it would not meet this definition of an authorized generic, carrying the marketing category NDA on the FDA's Comprehensive NDC SPL Data Elements (NSDE) File and not appearing on the FDA Listing of Authorized Generics.

Determining whether a higher tier actually has a lower cost-share may be more difficult if the plan must determine whether a co-insurance tier has lower cost-sharing than a copay tier. For example: Levothryoxine, the generic for Synthroid, is on Tier 2 ($20 copay). The negotiated cash price, which is what the beneficiary would pay, is $18. There are other thyroid products on tiers 3 ($45 copay) and 4 (50% coinsurance). The beneficiary asks for a tiering exception. There are no drugs to treat hypothyroidism on Tier 1; however, the tier 4 co-insurance would allow the beneficiary to pay only $9. Is it CMS' intent to allow beneficiaries to request tiering exceptions for generic drugs on the lowest tiers for a co-insurance at a higher tier if there is either a brand or generic to treat the same condition on the higher tier?

Recommendation: Including the specialty tier as the lowest cost-sharing tier is understandable when the enrollee's cost of the drug is based on co-insurance. Explaining to the enrollee that the lowest cost-sharing may be on a higher tier could be confusing, especially when the co-insurance on a higher tier would be less than the copay on a lower tier. While we agree that it is appropriate to approve a tiering exception for a drug with a co-insurance to a higher tier if the co-insurance on that tier is lower, we recommend that CMS not allow drugs with a copay to be approved to a tier with a coinsurance as this completely bypasses the formulary design. Additionally, allowing a drugs with a copay to be approved a tier with a coinsurance would require extensive review of negotiated prices resulting in additional burden when administering the tiering exception benefit. In order to assure that all plans explain this new process clearly and appropriately, it would be beneficial if CMS would include standard language for explaining tiering exceptions in the 2019 model Explanation of Coverage (EOC).

We also recommend that CMS allow plans to consider drugs to be generic drugs when they are treated as a generic by the plan (i.e., they have a generic copay, have a generic Multi-Source Code in a national database such as Medi-Span, and may be substituted for other brands).

10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries.

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We support the limitation of use of the dual eligible SEP to ONE per year. However, we recommend that CMS not introduce multiple eligibility requirements and complex criteria as proposed. Adding additional SEP criteria based on changes in level of subsidy, contract-type scenarios, reassigned or auto-facilitated enrollees would create confusion for enrollees, as well as, be administratively encumbering to plans to implement the many "if, then" scenarios required. In support, and as cited in the rule, the majority (74.5%) of those who have Extra Help currently use the SEP one time per year and most LIS beneficiaries do not initiate changes to plans, as over 71% are placed in other plans via the reassignment or auto-facilitated process by CMS. Therefore, limiting the election to ONE per year would help eliminate the small volume of individuals that are truly voluntarily changing plans (0.8%) monthly to incur a different benefit which would also promote continuity of care. To administer the SEP appropriately and reduce further operational burdens, we recommend that CMS use the existing SEP in place today for dual eligible beneficiaries for the one-time election per year to voluntarily change plans. For new enrollees, CMS would provide the determination of eligibility for the annual SEP on the Batch Eligibility Query (BEQ) process.

CARA Provision

In order to effect the part of the proposal in relation to CARA, we would support the proposed limitation to not allow the SEP for at-risk or potentially at-risk beneficiaries based on plan-required submission of POS data. CMS would provide plans the specific mechanisms to manage this limitation by providing a unique TRC for current plan enrollees when they are so-defined and passing the information on the Batch Eligibility Query (BEQ) response for those enrollees defined from a prior plan that are submitting an enrollment request. To properly and successfully administer, we emphasize that it would be critical for CMS to provide the specific data timely to plans to effect the appropriate denial of a submitted enrollment for the LIS-eligible SEP under this provision. Conversely, in cases where the at-risk period expires, or a favorable appeal outcome is determined, CMS would need to notify the plans via the above described mechanisms described based on plan-submitted POS data when the limitation is terminated and the SEP would be available to the beneficiary.

11. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System.

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CVS Health requests that CMS consider a number of changes prior to codifying the existing Star Rating System for MA/PDP.

Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated contracts:

CVS Health has identified opportunities to improve many of the current Part D Stars measures to ensure the Star Ratings System achieves its stated purpose of providing information to the beneficiary that is a true reflection of the contracts' quality, health outcomes and enrollee experience and to employ methodologies that minimize risk of misclassification.

The measures cited below have demonstrated methodological flaws that do not provide accurate reflection of a health plan's performance. These measures include:

- Measure D05: Members Choosing to Leave the Plan
- Measure D08: Rating of the Drug Plan
- Measure D09: Ease of Getting Needed Prescriptions
- Measure D04: Complaints
- Measure D01: TTY/Foreign Language Call Center Accessibility
- Measure D03: Appeals Upheld: Fairness of Plan's Denial
- Measure D07: Quality Improvement
- Measure D14: Medication Therapy Management

We recommend CMS employ a consensus driven approach to modify existing methods to address the flaws and/or replace these measures with others that may be more relevant.

Increased Weight of Patient Experience Measures to 3x

CMS is also proposing to increase the weight of patient experience/complaints and access measures. (1.0 to between 1.5 and 3 similar to outcome measures) to align with the goals of "patient first" and "consumer voice" guiding principles of CMS. CVS Health does not support an increase in weights to the patient experience set of Star measures. CMS has indicated that the Star measures should be selected based on plans' ability to influence them. Given that context, contracts have little control, if any, over the patient experience measures performance and increasing their weight will adversely impact plan performance with little added benefit to the beneficiaries. Highlighted below are examples of patient experience measures, Members Choosing to Leave the Plan, Rating of the Drug Plan or Getting Needed Prescriptions, and Complaints, that are not accurate reflections of a patient's experience with the contract's quality of services.

Measure D05: Members Choosing to Leave the Plan.

The methods used to measure members choosing to leave the plan do not achieve CMS' goal of measuring the plan's quality of service and beneficiary experience. Instead, this measure is primarily measuring plan pricing strategies and competitive market dynamics during the Annual Enrollment period. CVS Health recommends that CMS consider alternative measures that will more closely reflect the plan's quality of service and beneficiary experience. In the interim, we recommend moving this measure to the Display page.

Currently, CMS rates plans' member experience through a set of measures that includes the Part D measure, D05 Members Choosing to Leave the Plan or Voluntary Disenrollment from the

plan. The measure is based on disenrollment data captured through following disenrollment or TRR codes that include 11 - Voluntary Disenrollment through plan; 13 - Disenrollment because of enrollment in another Plan; 14 – Retroactive; and 99 - Other (not supplied by beneficiary). Performance on this measure is primarily influenced during Annual Enrollment Period, when the majority of voluntary disenrollment occurs.

While the TRR codes are an accurate data source to monitor the volume of members choosing to leave the plan, they do not provide insight into why members are choosing to leave. CVS Health member research of reasons for voluntary disenrollment indicate that up to 85% of an enrollee's reason for choosing another plan are cost and coverage of drugs, with ~55% of members citing a lower co-pay or monthly premium. The 2016 Medicare Prescription Drug Plan Disenrollment Reasons Survey Results issued by CMS substantiates our observation that cost is the primary driver of voluntary disenrollment vs. information or access. In this study, CMS asked enrollees about reasons for disenrollment. The report indicates that 74% of enrollees surveyed nationally cited financial reasons, such as cost or affordability of services, for disenrollment, with 50% citing two or more financial reasons for disenrollment. By comparison, when asked about problems with Prescription Drug Benefits and Coverage, only 18% of enrollees cited this as a reason for disenrollment.

As these studies demonstrate, this measure is primarily influenced by plan pricing strategies and competitive market dynamics during the AEP. However, if the intent is to measure pricing strategies and competitive market dynamics, then the measure is incomplete as it does not account for LIS lives that are re-assigned during AEP due to loss of benchmark.

Additionally, certain member segments are more likely to shop each year. For example, the 2016 CMS Disenrollment Reasons survey cites that LIS status and age have a strong relationship to voluntary disenrollment. Enrollees with dual eligible status had a voluntary disenrollment rate of 13%, which is >50% greater than non-LIS/dual eligible beneficiaries with an 8% voluntary disenrollment rate. Additionally, enrollees <65 years old have a voluntary disenrollment rate of 10%, which is 25% greater than enrollees > 65 years old with a voluntary disenrollment rate of 8%. As a result, the measure will be impacted based upon the membership composition of the plan.

As evidenced by the CMS reported voluntary disenrollment reasons report, this measure in its current form is highly influenced and impacted by the pricing strategies that plans use as a competitive advantage to attract membership during the AEP and by demographics of plan membership rather than the actual patient experience provided by the plan. We recommend that CMS revise this measure's specifications to accurately capture the member experience to ensure that the voluntary disenrollment was the direct result of the inadequate/unsatisfactory services and care delivery provided by the plan and not due to the PBP components such as cost and coverage.

Measure D08: Rating of Drug Plan;
Measure D09: Getting Needed Prescription Drugs

CVS Health opposes the proposed increase in the patient experience CAHPS measure set (i.e., D08: Rating of Drug Plan; D09: Getting Needed Prescription Drugs) weights from 1.5X to 3X. The current CAHPS survey measures do not provide an accurate reflection of member experience with the plan, and are highly influenced by contract pricing strategies or a general sense of confusion with the intent of the question. We recommend that CMS redesign the questions included in the survey, including but not limited to replacing single question measures with composite questions, to ensure that the responses reflect and qualify the service and care delivered by the plan and not penalize plans for care and quality unrelated aspects of the plan such as cost and coverage of drugs that are beyond plan's control. Furthermore, the calculation methodology needs additional refinements, e.g., provide visibility into statistical components such as "case mix adjustment", "Statistical Significance" and "Reliability" that have demonstrated impact on the measure performance calculation and final star assignment for this measure.

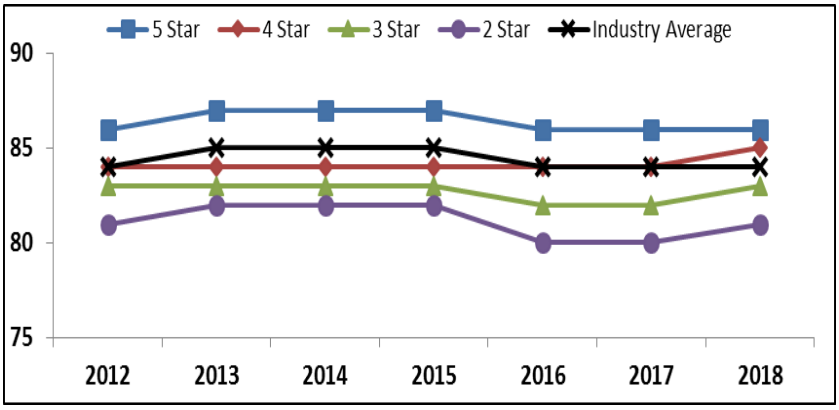
In an effort to gain insights into key drivers of this patient experience measure set and implement appropriate action planning, CVS Health has conducted an off-season survey for past three calendar years, following conclusion of Annual CMS CAHPS survey. We replicated the CMS methodology for this survey and included additional questions to garner deeper insights that may be driving member responses. Our off-season survey data analysis from the past two years indicate that >80% of a members' rating of drug plan was related to plan design factors including Cost, Coverage, Network Changes, and Drug Tiering. The examples below demonstrate that beneficiaries' responses are mostly driven by confusion with understanding their benefits and attributing their dissatisfaction with the cost and coverage of the plan, or broader health access challenges, rather than the service they received from their plan. Many of the reasons for dissatisfaction cited are beyond the plan's control, such as doughnut hole or not being able to afford gas to drive to the pharmacy.

Examples of member comments from S5601 Off-Season CAHPS survey include:

- *"They used to cover my drug. Now they don't."*
- *"It's not easy to understand costs."*
- *"It is a lot of money and I am on a limited income."*
- *"I am in the doughnut hole and I can't seem to get out."*
- *"I have trouble getting my prescription. I do not have gas."*
- *"When I go to the pharmacy, sometimes I have to wait. I don't like that."*
- *"I don't understand why I can only get some prescriptions for 90 days."*
- *"Well, the last two prescriptions I could not fill them because I could not afford them because of the doughnut hole. One was $600 and the other was $1000. That's the reason I could not afford it."*
- *"Lower the price of the Breo Ellipta medication."*
- *"I just do not like the fact that there is a third party involved when I need my prescriptions."*

Finally, CMS should consider these measures as "topped out" with little room for improvement. As evidenced below, the industry performance and Star level cut points have remained relatively stable over the last 7 years. Unless CMS addresses the underlying flaws in the survey methods, (i.e., asking broad questions without context), contracts' ability to influence the measure will remain limited, and performance will be stagnant.

Measure D08: Rating of Drug Plan, MAPD Industry Average Performance and Star Level Cutpoints.



Conclusion:
We urge CMS to consider alternative CAHPS survey questions to elicit member responses that more closely reflect their experience with the drug plan and the plan's ability to provide the necessary and timely service and care needed by the beneficiary. Until new methods are tested, CMS should reduce the weighting or moving this measure to the display page.

Measure D04: Complaints about the Drug Plan.

CVS Health recommends that CMS considers the following improvement opportunities as it relates process improvement in order to reduce the inconsistencies in the CMS Complaint Tracking Module (CTM) process that have a demonstrated impact on a contract's action planning and performance on this measure.

We have identified the following areas including potential improvement opportunities within the CMS CTM process. We are providing an explanation and suggestion for each of the identified process challenges. These suggestions are made on the basis that the contract has seen inconsistencies with the manner in which each of the CMS Regional Offices handle various scenarios that have not been outlined in the CMS CTM SOP. Therefore, we are providing several suggested edits, in an effort to mitigate commonly noted discrepancies. These discrepancies undermine the data integrity of the Star Ratings measurement of Complaints, which is a critical measure gathering beneficiary experience with a plan's services. We strongly urge CMS to implement appropriate process guards and conduct continual monitoring to identify additional opportunities to eliminate future discrepancies.

Process Highlight: CMS/SSA system issues or enrollment logic disputes.
These are examples of complaints where issues have occurred, due to gaps within CMS and SSA systematic processing policies and defined logic rules. These process gaps ultimately caused impact to beneficiaries through unintended eligibility actions, financial deductions or rejection of a requested action.

> **Concern:** On occasion, errors or limitations of CMS systems occur, which can have downstream impact that causes complaints to be filed against plan sponsors.
>
> **Recommendation:** An excluded category/sub-category should be created for use when the dispute is related to a CMS caused issue or system limitation.

Process Highlight: 1-800-Medicare provided incorrect / incomplete info.
These are complaints where the 1-800-Medicare Beneficiary Contact Center (BCC) provided inaccurate or incomplete information, that mislead the beneficiary with regards to various aspects of the Part D benefit design.

> **Concern:** When it is stated in the complaint, or the plan sponsor determines that the issue was the fault of a 1-800-Medicare Representative, there are currently no provisions outlined to return the complaint to CMS for follow-up or closure.
>
> **Recommendation:** The CMS CTM SOP should be revised to provide instructions for plans to return issues determined to be error by 1-800-Medicare, as a CMS issue for follow-up with the representative who caused the complaint, or closure.

Process Highlight: Misrepresentation allegation or enrollment dispute against another plan sponsor or other entity (CMS/SSA/SHIP/SPAP/LTC/etc.).
This topic includes complaints where an entity, who is not licensed to sell the plan sponsor's insurance policies, or someone who is not contracted with or working on behalf of an entity outside of the plan sponsor, submits enrollment on the beneficiary's behalf; either without the intent of the beneficiary, or having provided information that misrepresented the plan design.

> **Concern:** The current CMS CTM SOP indicates that "Plans should not submit Plan Requests seeking re-categorization of marketing complaints."
>
> **Recommendation:** The CMS CTM SOP should be revised to indicate that, if the outcome of review of a misrepresentation or enrollment dispute determines there is no fault of the plan, plans should return complaints to CMS for closure as a CMS issue, or reassignment to the appropriate entity, if available.

Process Highlight: Educational issue / Referral from SSA/CMS Entity for Assistance (No Plan Fault).
These are complaints that were submitted with the intention of aiding a beneficiary through a CMS related process, with no occurrence of erroneous action having taken place on the plan sponsor's end.

Concern: Many times CTMs are entered as a request or referral to the plan, or educational (non-complaint) request. These cases are typically entered in category / sub-category combinations that count against the plan's metrics.

Recommendation: We suggest that CMS create an excluded category intended for cases that are educational and/or are referrals to the contract.

Process Highlight: Duplicate complaints.
These are complaints that were actively in the process of review and resolution, when an identical complaint was submitted, or identical complaints were received on the same day.

Concern: The current CTM SOP advises the contract to close duplicate complaints. Some instances where duplicate complaints are not appropriate to be counted against the plan sponsor on multiple occasions are the complaints that may be an identical copy received from multiple sources, as a submission of additional information from 1-800-Medicare on the same call and complaints that are filed to 2 different plan sponsors with the other plan requesting that their case be forwarded to the other sponsor.

Recommendation: The CMS CTM SOP should be revised to provide alternate options for scenarios where complaints have been duplicated. The SOP should provide scenarios when it is appropriate to return these duplications as a CMS issue, or reassignment to another entity, if appropriate.

Process Highlight: Assignment / Reassignment date.
Complaints that were submitted to CMS as a plan request by the plan sponsor and returned to the plan are subject to either having the assignment / reassignment date reset to the current date, or remain as the original assigned date, depending on the actions of the CMS Caseworker.

Concern: The CMS CTM SOP does not define situations when a case assignment / reassignment date should be reset by the CMS Caseworker. This ambiguity can lead to plan requests being 'rejected', in order to return the case to the plan, even when CMS has agreed with the plan's request and has made the necessary changes. This ultimately causes cases to appear as if they have exceeded the permitted turn-around-time, despite CMS agreeing to the request.

Recommendation: The CMS CTM SOP should be revised to provide clear processes for when the assignment / reassignment date should be reset by CMS, so that plan sponsors can better strategize their actions.

Measure D01: Call Center – Foreign Language Interpreter and TTY Availability:

CVS Health recommends that CMS revise the sampling methodology for this measure. In its current form, the sampling done by CMS to determine (a) the Accuracy and Accessibility study at the Call Center Level, and (b) Availability of TTY Services and Foreign Language Interpretation When Prospective Members Call the Drug Plan, has demonstrated flaws that result

in inaccurate and unfair representation of the call center services provided to current and prospective Medicare beneficiaries.

(A) Sampling Method to Determine Overall Testing Volume.

We recommend that the test calls for Accuracy and Accessibility study consider contract's enrollment size in addition to the number of physical locations of call centers serving the contract when determining sample size. Currently, for the Accuracy and Accessibility study at the Call Center Level conducted by CMS annually, the test call sample is pulled based on the "physical" locations of the call centers that serve the contracts (and plans under that contract) and does not consider the contract size. As a result, each call center receives the same number of calls regardless of the enrollment size of the contracts and plans associated with the call center.

The sample design falsely assumes that there is no correlation between enrollment size and expected variance of the key metrics. In our experience, as the enrollment size of the call center/contract increases, the variability in the key proportions (e.g., the percent of accuracy questions answered correctly) also increases due to increased chance of human error amongst a larger pool of call center representatives, which can occur despite strong processes and oversight. Contracts serving larger enrollment volumes employ a broader pool of representatives to serve their membership. Not all contracts have a model that distributes these representatives across physical call center locations; and so CMS' approach to sample based upon number of physical locations does not adequately sample to account for variability amongst a broader pool of representatives. CMS' current approach favors contracts who distribute representatives across multiple physical locations. These contracts will receive more test calls, which increases the margin of error allowed within the study. CMS should address this bias that results from the flawed assumption in sampling methods by considering contract enrollment when determining testing sample size.

(B) Sampling Method to Determine Testing Volume by Language.

CVS Health recommends that the number of Foreign Language Interpretation availability test call made by "secret shoppers" for each of the languages tested be in alignment with the demographic landscape as to proportion or prevalence of such languages spoken in this segment of the population.

According to the 2014 data release by the American Community Survey (ACS), an ongoing survey implemented by the U.S. Census Bureau, approximately 8% of population (i.e., approximately 4 million people), 65 and older speak non-English as their first language or have Limited English Proficiency (LEP)[1]. As to the proportional breakdown of the top foreign languages spoken in this group, in descending order, are noted in the table 1 below.

[1]Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf (Accessed December 15, 2017) https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf

Table.1. Census Data - Top languages spoken at home by the 65 and older demographic along with their respective percentage share compared to the entire non-English speaking language population.[1]

Foreign Language	Population	Percentage out of LEP population that speaks non-English as their first language
Spanish	2,112,135	52%
Chinese	213,619	5%
Vietnamese	163,678	4%
Tagalog	143,944	4%
Korean	138,976	3%
Russian	136,976	3%
Italian	103,163	3%
Cantonese	82,078	2%
French Creole	62,058	2%
Other		22%

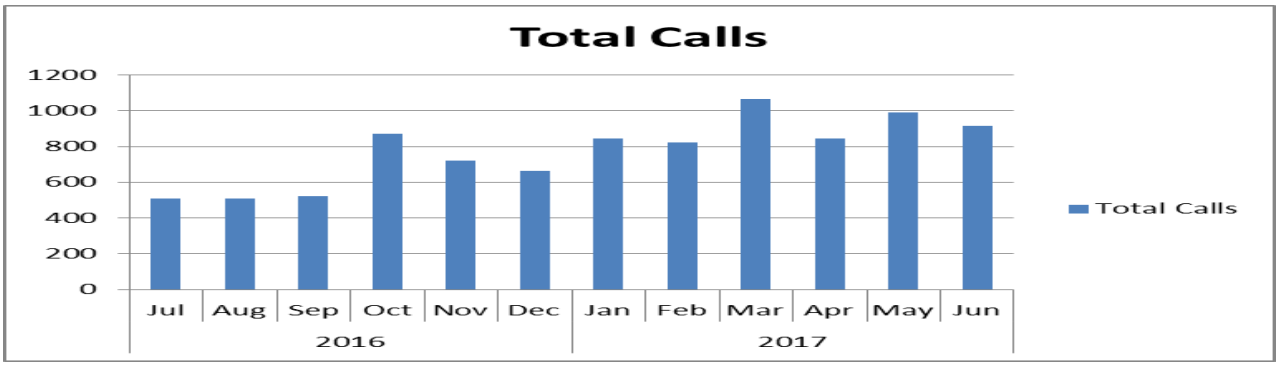
Observations and Implications:
There are over 2.1 million people or 52% of total non-English as a first language speakers age 65 and over who speak Spanish at home compared to the 143,944 or 4% who speak Tagalog. Based on the SilverScript Foreign Language Accessibility test call results this year, while Spanish is the most common language among the U.S. population, it was one of the languages tested least by CMS. In comparison, Tagalog, was tested more frequently as seen in the table below. Furthermore, the current set of foreign languages required and tested for interpreter availability do not align with the prevalence of foreign languages spoken in this demographic segment. Korean and Russian are more prevalent than Cantonese and French but CMS does not include these languages in the testing.

2018 Star Ratings Results: S5601 – SilverScript Foreign Language Test Call - Volume and Percentage of Total Calls.

Foreign Language	Number of Calls	Percentage of Total Calls
Mandarin	13	21.31%
French	11	18.03%

Vietnamese	10	16.39%
Tagalog	10	16.39%
Spanish	9	14.75%
Cantonese	8	13.11%
Total	61	100.00%

The Year-over-Year (YoY) trending, with number of calls per month for 2016 and 2017 calendar year for SilverScript Insurance Company (S5601) of the "Total foreign language calls."



Furthermore, because the number of "secret shopper" calls for foreign languages is disproportionate to the overall Medicare population, it creates an artificial surge in demand during the test period as seen the Figure 1. The individual charts highlight the spike in demand for foreign language prospective enrollment interpreters observed by SilverScript during the 2017 CMS test period, primarily during the month of March. The demand during the CMS test period exceeds the peak demand experienced in all other months, including the Annual Enrollment Period (AEP).

In summary, we recommend that CMS revise the languages included and the testing frequency to ensure that the testing results accurately reflect the Medicare beneficiary experience. Based on the evidence provided above, the current methodology should be revised to ensure foreign language testing volumes align with languages most commonly spoken by Medicare beneficiaries; and consider aligning foreign language testing volumes to the demographics served by the contract.

Measure D03: Appeals Upheld:

We appreciate and support CMS' stated objective of ensuring that the Star Ratings accurately reflect plan quality. To support CMS in achieving this, we are raising our concerns and supporting evidence that the methodology utilized for the D03 measure, The Measure of Appeals Upheld: Fairness of Drug Plan's Appeal Decisions, is not accurately measuring how often an Independent Reviewer found the drug plan's decision to deny an appeal was fair.

Current D03 Appeals Upheld measure methodology does not account for the change in clinical status or the change in the prescriber request that can occur during the time period from when the contract decisions a case for redetermination (RD) to when the Independent Review Entity (IRE) decisions a case. Change in case status can result in a different decision by the IRE than the decision reached by the contract. While the decisions are different, they may both be appropriate based upon the status of the case or the information available at the time of review. The measure methodology does not currently account for this appropriate difference in decision; thus our concern that the measure methodology does not meet its intended purpose of measuring the extent to which the contract's decision to deny an appeal was fair. Instead, the measurement, as currently designed, measures what is approvable at the point in time that the IRE reviews the case, which can be two months after the date of the contract's decision.

In fact, for SSIC, the contract reached accurate and timely decisions on numerous cases during the 2017 plan year that were overturned on appeal to the IRE. Upon the contract's detailed review of these cases, it was uncovered that many overturns were due to (1) changes in clinical status; (2) changes in prescriber request between the timeframe that SilverScript reached its decision on the case redetermination (RD) and when the IRE evaluated and reached a decision on the case; and (3) inconsistencies in the IRE's review of similar case types. The trends outlined below with supporting case examples illustrate the flaws in the current measure methodology.

We fully support the IRE making the most accurate and timely decision on behalf of the member based upon information available at the time of review. However, we are strongly opposed to the appropriate IRE decision counting against the contract on the D03 measure if there was a notable change in clinical status or prescriber request with the case following the contract's accurate and timely decision. We request CMS' consideration of two potential solutions to support closer alignment to the measurement of the fairness of the contract's decision based upon the status of the case at time of contract decision:

(1) The IRE could render two decisions on the case: one decision would be for the enrollee's appeal based upon the most current information the IRE has received; the other decision would be on the fairness of the contracts'decision based upon the status of the case and information available to the contract at time of decision. Only the latter decision would be used to support the DO3 measurement of Fairness of Drug Plan's Appeal Decision.

(2) Alternatively, CMS could create clear exclusion criteria for scenarios where the patient's status or the prescriber's request has changed from the time the contract decisions the case to the time the IRE decisions the case. The subsequent examples illustrate potential exclusion

scenarios. In the instance that a case meets the exclusion criteria, the case would be excluded from the contracts' D03 measurement of Fairness of Drug Plan's Appeal Decision.

Notable trends of concern in 2017 plan year include the following:

1. **Not all Clinical Information considered by IRE during review.**
   In these instances, the IRE overturn was based on the IRE not taking all clinical information presented into consideration with review. The overturn was based on the potentially 'approvable' aspects of the case, but failed to take additional clinical information provided into consideration that would have led to the plan being upheld had additional clinical information been appropriately considered. The contract should not be penalized for making an appropriate denial decision based on the information presented to them at the time of decision making.

   - Ofev (1-5976366185):
     - The contract's denial at the RD level was based on answers to the PA criteria questions that the enrollee had a known underlying cause of their lung disease. Additional information was received from the prescriber's office where the clinical staff verified that the underlying cause of this enrollee's pulmonary fibrosis was sarcoidosis. By definition, the diagnosis cannot be idiopathic if an underlying cause is known. Pulmonary fibrosis due to sarcoidosis is *not* a CMS compendia supported indication for the use of Ofev. The IRE did not acknowledge that the enrollee had an underlying cause for their pulmonary fibrosis. The approval from Maximus was based on a diagnosis of 'idiopathic' pulmonary fibrosis without addressing the information sent to them in the IRE file that mentioned the previously indicated sarcoidosis.

   - Gammunex-C (1-6990814639):
     - The IRE overturn for coverage under Part D (as opposed to Part B) was due to the IRE only taking some of the provided diagnoses into consideration during review. The Prescriber had submitted a Part B eligible diagnosis (D83.8) to the contract but it did not appear to be evaluated by the IRE.

2. **Approval granted when new laboratory information was available to IRE after date of RD denials.**
   In these instances, the IRE received new or updated laboratory information that now allowed the case to meet PA criteria requirements. The contract would have approved these cases if the prescriber had sent this same information to the contract that they sent to the IRE.

   - Natpara (1-6391901643):
     This case was denied by the contract due to lack of confirmation of normal magnesium levels (the lab results were still pending at the time the case was initiated with the IRE). The prescriber provided the normal magnesium level information to the IRE, and the IRE overturned the case on the basis that the patient labs results showed a normal magnesium level. The contract's decision at the time of the RD denial was accurate.

- Axiron (1-6403250230) and Androderm (1-6790209437):
  These cases were denied by the contract due to lack of two laboratory test values confirming a low testosterone level. The IRE approved the cases due to the new laboratory values being submitted to the IRE. The contract's decisions at the time of the RD denials were accurate

3. **Maximus reviews a request for different regimen than what was requested of the contract.**
   In these instances the contract reviewed and made a determination based on a different regimen than the regimen the prescriber requested at the IRE level of review. We propose that requests for new regimens [at the contract level] should be considered new requests. When the case presented to the IRE is for a different regimen than the one presented to the contract, we propose that it should be handled as a new request and remanded back to the contract.

   - Ninlaro (1-5948601059):
     This case was denied by the contract as the Prescriber had indicated Ninlaro would not be used in combination with Revlimid and dexamethasone. This regimen was confirmed with the office at Redetermination. Maximus' Physician review indicated that the regimen had been 'changed' to Ninlaro + Revlimid + dexamethasone – a new regimen and one that would have met criteria under contract review. This represents a new case and should have been handled as such.

   - Zepatier (1-5844993547):
     The contract issued an unfavorable decision for coverage because the requested regimen of Zepatier and Ribavirin was not supported for the enrollee's clinical status (Hepatitis C, treatment naïve, genotype 1b with compensated cirrhosis). Maximus reviewed as Zepatier monotherapy instead of Zepatier plus Ribavirin combination therapy; claims history at the time of the contract's RD review showed that the patient has still been receiving Ribavirin, so the enrollee in fact was not on a Zepatier monotherapy regimen at the time of the RD request.

   - Afinitor (1-6735857236):
     This case was denied for lack of medical necessity (no support in CMS approved compendia/journals) for the requested regimen of Afinitor plus Faslodex in an HR+, HER2 – individual. The prescriber provided support in the form of a symposium presentation, which is not considered an acceptable compendia source. The IRE reviewed a different regimen of Afinitor plus exemestane, which is supported by compendia and meets criteria. The case was appropriately denied by the contract on the initial regimen requested, since there was no CMS approved compendia/journal support. The different regimen represented a new case, and should have been referred back to the contract for evaluation. If the contract had received this new regimen request, it would have been approved.

4. **Approval granted based on clinical assumptions.**
   In this instance, an approval was granted by the IRE on the assumption that the patient 'likely' had a diagnosis or condition despite a prescriber's statement to the contrary to the contract. Our position is that neither the contract nor the IRE should make diagnostic judgment/assumptions for the prescriber.

   - Testosterone (1-6059481715):
     Contract's denial was based on prescriber's indication that patient has neither congenital or acquired primary hypogonadism nor congenital or acquired hypogonadotropic hypogonadism. Maximus' approval stated that the patient's testicular hypofunction is 'likely' acquired primary hypogonadism but did not provide any clinical documentation or indicate that they obtained clarification to support that assumption.

5. **Tiering eligibility granted despite lack of clinically comparable alternatives on formulary.**
   This is an example where Maximus granted a tier exception for the presence of lower tier alternatives that were not clinically comparable to the requested medication and in fact not on the contract's formulary.

   - Restasis (1-6030745349):
     The contract issued a denial on the basis that no lower tier alternative exists for the treatment of the patient's dry eye syndrome of the bilateral lacrimal glands. Maximus issued a favorable decision on the basis that "all available lower tier alternatives on the plan's formulary (artificial tears) would not be as effective/have adverse effects". However, artificial tears are available over-the-counter and would be excluded from coverage under Medicare Part D. Moreover, neither artificial tears, nor any other comparable alternatives, are available on the plan's formulary at a lower tier. The IRE's favorable decision was made without verification that a comparable lower tier alternative existed on the contract's formulary.

6. **Issuing favorable decisions due to timing of compendia updates.**
   In this instance, Maximus granted an approval based on Medicare approved compendia support present at the time of their review when that same support was not present at the time of the contract's review. While this case specifically involves DrugDex, it also applies to other Medicare approved resources, such as NCCN, FDA-label updates, etc. that occur after the date of the contract's review. The contract should not be penalized for compendia updates that occur after the contract's review.

   - Mycophenolate mofetil case 1-6979691659):
     The contract issued an unfavorable decision at both coverage determination and redetermination regarding coverage due for treatment of a non-compendia supported indication (autoimmune hepatitis). At the time of the contract's review, there was no compendia support for this off-label use. We agree that the IRE made the correct decision at the time of their review. After the date of the contract RD review, CMS compendia was updated with a new citation that supported the off-label use of

mycophenolate for autoimmune hepatitis. The contract should not be penalized for compendia updates that occur after the date of the contract's review.

7. Different information being supplied to the contract by the Prescriber versus what the Prescriber supplied to the IRE.

This scenario of concern refers to the situation when the cases are appropriately denied by the contract based on information supplied by the prescriber/office, and overturned by the IRE when the prescriber gives new/different and often conflicting information to the IRE. If a new coverage determination request had been submitted to the contract with this new information, the contract would approve based on the fact the case would now have met requirements. Since there can be a two month time frame from redetermination denial to IRE appeal, the clinical situation could have changed, lab tests could have been performed, etc. after the contract's decision. Because the IRE has to perform a de novo review, they may make a different decision than the contract, even when they recognize that the contract's decision was correct based on the information that was available to the contract at the time. Our position is that the different decision reached by the IRE in this scenario should not count against the D03 measurement for the contract.

- Nuplazid (1-6672876949):
  The contract denied the case because the prescriber stated the patient had dementia-related psychosis but it was unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis. After the RD denial, the IRE overturned the case because the prescriber told the IRE that it was associated with the member's Parkinson's disease psychosis, the opposite of what they had told the contract. Both the contract and the IRE made correct decisions based on the information available to them at the time of the decision.

- Lidocaine Patch (1-6744536039):
  Denied for diagnosis of joint pain and thumb fracture. Prescriber put a note in the member's chart about two weeks after the date of the RD denial that the patient now has diabetic neuropathy and that this was the reason for the request. The IRE approved based on the new diagnosis. Both the contract and the IRE made correct decisions based on the information available to them at the time of the decision.

- Zepatier (1-6285998965):
  The IRE stated that the contract was correct in denying the initial request, as the contract requires NS5A testing which had not been done prior to review. The enrollee had the testing done after the RD denial date. Since the criteria was now met, the case was approved by the IRE. Both the contract and IRE made correct decisions at the time they reviewed the case.

- Lupron (1-5886647948):
  The IRE favorable response stated the following: Lupron is being used for initial treatment and not retreatment. Use of addback therapy is only required for retreatment. This information satisfies the coverage criteria. (The IRE stated that the

contract had sufficient information to approve if the prescriber's office had correctly indicated this was initial treatment and not retreatment, which was not the information the plan received). Despite the IRE recognizing that the contract had been given incorrect information, the IRE had to make a de novo decision. The contract should not be penalized when they receive incorrect information from the plan. Both the IRE and the contract made correct decisions, based on the information presented to them at the time of their review.

Measure D07: Drug Plan Quality Improvement (QI); Application of the Improvement Measure Scores:

CVS Health is supportive of the inclusion of Quality Improvement (QI) measure and considers it as a defining feature of the Star Ratings System. However, we remain highly concerned about the underlying method flaws that do not allow a fair and equitable opportunity for the high and low performers, given there is limited room for improvement for high performers compared to their low performing counterparts. Additionally, we urge CMS to review the measures that are included as a part of the QI measure calculation to ensure that, (1) performance improvement on these measures is under control of the plan;, and (2) that performance has not topped out on these measures, resulting in little to no opportunity to improve performance.

The CMS Star Ratings program continues to drive quality improvement across the Medicare Advantage and Prescription Drug Plan industry that is evident in recent 2018 Star Ratings results wherein no single contract received a Low Performing Icon (LPI). As industry performance on Star Ratings continues to improve, the opportunity for improvement decreases and becomes more difficult, especially for high performing contracts. Our concerns with the current approach to QI measurement include the following flawed assumptions as to measure design and calculation:

(1) Plans have equal opportunity to drive continued improvement YoY for mature measures as for new measures.
(2) High performing plans and low performing plans have equal opportunity to drive continual improvement in performance across all measures in a YoY improvement effort**.**
(3) The "hold harmless" acts as a safeguard to protect plans that have some incremental improvement when the improvement opportunity is maxed out.

To adjust for these flawed assumptions, we recommend CMS consider one of the following three adjustments to refine the Quality Improvement measure:

(1) Evaluate performance on a log scale instead of a linear scale.

Below are examples of how the opportunity to improve diminishes as performance approaches the measure's highest possible performance level:

Example of Low Performance:

	2015	2016	2017	2018
Contract A Metric	70%	72%	74%	76%

Year over Year Delta		2%	2%	2%
Opportunity (100%-Metric)	30%	28%	28%	26%

Example of High Performance:

	2015	**2016**	**2017**	**2018**
Contract B Metric	80%	82%	84%	86%
Year over Year Delta		2%	2%	2%
Opportunity (100%-Metric)	20%	18%	16%	14%

Currently, CMS calculates YoY improvement on a linear scale; however, performance improvement is rarely evenly incremental. Given the law of diminishing returns, as performance improves, continued improvement becomes difficult to achieve. CMS should reward contracts with an incentive that takes into consideration the level of effort it takes to improve from 4 to 5 Star performance levels vs. from 2 to 3 Stars performance levels and the baseline from which the plan improved in and YoY improvement effort. The example above demonstrates the continued difficulty to achieve higher metric level adherence scores as plans continue to improve their performance each year. Each mock contract above is improving adherence by two percent each year, but contract A has a greater opportunity to improve available, as compared to contract B due to contract A's performance starting at much lower baseline compared to contract B.

We recommend CMS use a logarithmic scale to evaluate year-over-year performance improvement. For example, a revised calculation formula could be:
log (10 x (absolute value (year-over-year change))) = Improvement Change Score

Unlike the linear scale, the log scale accommodates the law of diminishing returns and reduced improvement opportunity. By aligning the incentive to drive improvement with regard to the level of difficulty, plans will be incentivized to strive towards the highest levels of performance.

(2) Weight improvement achieved relative to current performance.

As another alternative approach to account for the law of diminishing returns noted above, CMS could consider applying a weight to the final Improvement Change Score for an individual measure within the Quality Improvement Model that takes into account the improvement performance level achieved by a contract when compared with the previous year.

For example, if a contract began with a 2 Star performance level and moved to 3 Star performance level, then their Improvement Change Score would be multiplied by the weight 1. In contrast, if a contract began with a 4 Star performance level and moved to 5 Star performance level, then their Improvement Change Score would be multiplied by the

weight 4, which would acknowledge the increased difficulty in moving from 4 to 5 in comparison with moving from 2 to 3.

CMS would need to develop the weighting system based on the data that is already at its disposal.

(3) Adjust the threshold for what is considered an improvement relative to the contract's level of performance.

Today, CMS calculates significant improvement/decline with a confidence interval of 95% for all contracts, regardless of their current performance:

(Improvement Change / Standard Error of Improvement Change) > 1.96
Significant Improve

(Improvement Change / Standard Error of Improvement Change) < -1.96
Significant Decline

In early days of QI implementation, the industry had significant room for improvement when a majority of the industry had a lower baseline; however, as the program matures, many contracts have less room for improvement as they achieve high performing status. We recommend CMS adjust the calculation to calculate significant improvement based off of a confidence interval of 90% for contracts that have achieved high performing status on this measure (i.e., 4 Stars or greater).

(4) Modify the hold harmless provision.

To account for the law of diminishing returns noted above, as well as protect high performing contracts from being penalized for lack of performance improvement once they achieve 5 star performance at a measure-level, the provision of "hold harmless" was introduced at the measure-level as well at the contract-level.

The "hold harmless" provision at measure-level is, "If a contract demonstrated statistically significant decline (at the 0.05 significance level) on an attainment measure for which they received five stars during both the current contract year and the prior contract year, then this measure will be counted as showing no significant change. Measures that are held harmless as described here will be considered eligible for the improvement measure".

Our modeling of the Quality Improvement measure requirements indicates that there are instances where a contract's performance on a measure would need to exceed 100% to attain Significant Improvement, however, the contract would not be held harmless because the measure performance had not attained 5 Stars. For example, D03: Appeals Upheld measure with metric score at 84.6 falls at 4 Star based on 2018 Stars published cut points. To achieve significant improve for 2019 Stars, our modeling indicates that the metric performance would need to exceed a metric of 100%, which is unattainable. Anything under 105 will result in "unchanged" status for YoY performance

improvement. Since the current performance is not at 5 Star level, the measure-level "hold harmless" provision will not apply. As a result, the contract is penalized with "Unchanged" performance even if they attain meaningful improvement up to 100% performance on this measure.

In its current form, the hold harmless provision is insufficient to address the underlying measure flaws in the QI calculation. An adjustment factor for situations noted above needs to be included in the QI calculation to reward the contracts that show incremental improvement in the performance but do not qualify to benefit from the hold harmless provision.

Taken together, we recommend that CMS considers the following adjustments as a part of the revised QI measure:

- Evaluate performance on a log scale instead of a linear scale;
- Adjust the threshold for what is considered an improvement relative to the contract's level of performance;
- Weight improvement achieved relative to current performance; and
- Adjustment factor for contracts that show incremental improvement at measure-level but cannot attain "Significant Improve" due to performance requirement above 100% and when hold harmless provision cannot be applied.

As the Stars Rating Program evolves, we request that the Quality Improvement methodology adapts to both encourage underperforming contracts to meet CMS standards and reward high-achieving contracts to strive for further excellence.

Measure D14: MTM Program Completion Rate for CMR

CVS Health urges CMS to move away from MTM process measures and looks forward to inclusion of outcomes-based MTM measures in the Star Ratings Program in the future. In the interim, we recommend CMS evaluate changes to the MTM Comprehensive Medication Review Completion Rate (CMR) measure methodology.

Small, geographically focused contracts and contracts with unique arrangements with provider networks have historically been able to achieve a higher completion rate with a substantially lesser degree of effort than large contracts that span multiple regions. Contracts with low enrollment can target a very small population of beneficiaries and achieve a high CMR completion rate. For example, if a 500 beneficiary contract has 100 members that qualify for the MTM program based on the contract's criteria, the completion of CMR's for only 50 members will result in a CMR rate of 50%.

However, contract with higher enrollment across multiple geographies face challenges to achieve a comparable CMR rate. As the absolute number of targeted beneficiaries increases across different geographies, the complexity of achieving a comparable CMR completion rate increases as well. Additionally, contracts with lower enrollment tend to have a closer affiliation with the

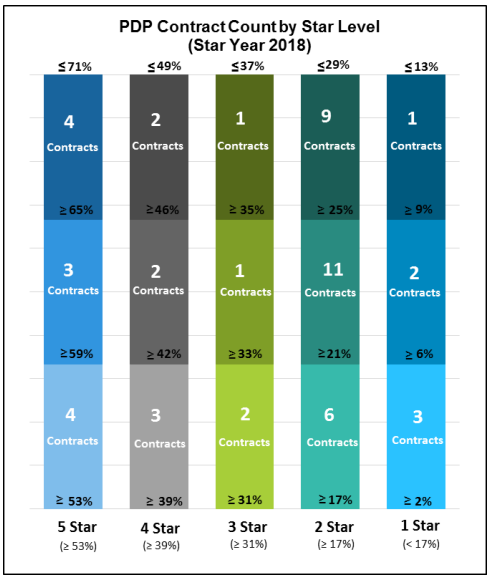
member due to their geographical focus near the member's home. For example, a contract that has a regional focus is more likely to have an affiliation with an ACO. This affiliation could increase the contract's ability to reach the member and prescriber to conduct a CMR, which would offer an advantage over contracts that do not have this unique arrangement.

We are concerned that the focus on volume of CMR's completed incentivizes contracts to narrow their targeting criteria for patients who should receive this service. We are also concerned that misaligned incentives that reward volume could result in lower quality of CMRs being performed in order to achieve the rates desired.

Analysis of 2018 CMS Star Ratings PDP industry data for the MTM measure, as shown below, demonstrates that high performance on this measure has a close relationship to the contract size. The Average Enrollment of PDP contracts earning 5 Stars is ~25% of the Average Enrollment of PDP contracts earning 3 Stars. In even starker contrast, the Average Enrollment of the 21% of contracts earning 1 Star was 52x the Average Enrollment of 5 Star contracts. As evidenced through the analysis below, smaller contracts are driving cut points upward, while larger contracts who face significantly greater challenges to achieve similar completion rates across diverse geographies and demographics are anchored at the 3, 2 and 1-Star level.

Measure D14: MTM Program Completion Rate for CMR; PDP:

PDP focused Contract-level performance landscape across the 5 star level cut points for MTM Program Completion Rate for CMR measure. The bar graph on the left shows the intra-star level distribution of contracts based on metric score range for each Star cut point while the table of the right provides the key highlights to support the observations in the bar graph (i.e., size of the contracts, % LIS burden, Maximum metric score for a Star level, etc.) along with the 2017 Stars data for each Star level as a comparative reference.



STAR_LEVEL	Contracts	Avg. LIS*	Avg. Size*	Min Score	Max Score	Median YoY Change
5 Star						
2018 Star Year	11	4%	26,573	53%	71%	16%
2017 Star Year	4	4%	67,224	52%	58%	
4 Star						
2018 Star Year	7	3%	29,561	39%	49%	4%
2017 Star Year	13	8%	40,403	34%	47%	
3 Star						
2018 Star Year	4	13%	110,872	31%	37%	10%
2017 Star Year	22	23%	576,221	20%	31%	
2 Star						
2018 Star Year	26	20%	507,410	17%	29%	1%
2017 Star Year	6	2%	22,892	13%	19%	
1 Star						
2018 Star Year	7	21%	1,385,923	2%	13%	0%
2017 Star Year	12	22%	838,894	0%	10%	

Conclusion:
Based on the evidence shared above, we urge CMS to consider replacing the current process measure with outcome-based and/or patient-experience based MTM measures, such as those that are currently under development by the Pharmacy Quality Alliance (PQA)'s MTM task force.

The two measures under development are:

- Next Generation MTM Measure: Diabetes (an Outcome-based measure)
- MTM: Medication Therapy Problem Resolution (A Patient Experience-based measure).

CVS Health recommends that CMS partner with PQA to develop and understand the feasibility of implementing the outcome and/or patient-experience based MTM measures, especially in regards to the Next Generation MTM Measure: Diabetes, given the increasing prevalence and downstream impact of this disease state. We strongly feel that outcomes measures such as the above are better aligned with the quality of care provided to beneficiaries through an MTM interaction and overall impact on health outcomes. Until outcomes based MTM measures are adopted, we recommend CMS consider adjustment to the measure to evaluate true differences in plan performance. CMS could consider adjustments based on contract size, targeting criteria, overall health of the population, and geographical location to solve for differences in number of members who qualify for the measure and a plan's ability to complete the CMR.

Display Measure: High Risk Medication (HRM).

CVS Health supports CMS's current policy to remove the High Risk Medication (HRM) measure from the Stars Ratings and position it on the Display Page. We appreciate CMS' commitment to provide sufficient lead time in relation to any changes to the Star Ratings. We request that CMS continue to ensure that any changes announced during the current measurement period are not implemented until at least the following measurement period.

Impact of Audits and Enforcement Actions on Star Ratings Program
Data Sources:

CMS proposes that the type of data used for Star Ratings will be data consistent with the data required by the statute to be submitted by MA organizations and Part D plan sponsors, and to require MA organizations and Part D plan sponsors to submit unbiased, accurate, and complete quality data. While CVS Health supports the proposal to codify the already existing practice into regulatory provision that requires MA organizations and Part D plan sponsors to submit unbiased, accurate, and complete quality data, CVS Health strongly opposes inclusion of audit results and enforcement actions as a data source within the Star Ratings program.

CMS' inclusion of audit findings and enforcement actions within the Star Ratings program does not provide beneficiaries with transparent, timely insight into plan quality performance and potentially reduces funding available for beneficiaries enrolled in a plan that would otherwise receive high performance on quality outcomes and resultant payments. To our knowledge, the agency has not done the analytic work to establish the scientific basis of any relationship between audit findings, deficiencies resulting in civil monetary penalties (CMPs) and quality of patient care or health outcomes. Further, CMS has not provided transparency into the

methodology that will be used to assess data integrity penalties from audits, outside of the Timeliness Monitoring Study.

Audit findings and enforcement actions can impact Star Ratings in multiple ways, such as the assessment of data integrity penalties that automatically downgrade measure performance to 1 Star and through specific measures, such as the Beneficiary Access and Performance Problem (BAPP) measures. While CMS has agreed not to reinstate the reduction to the overall and summary Star Ratings for contracts under sanctions for 2018 Stars, and has agreed to move the BAPP measure to the Display Page for 2019 Stars, Star Ratings results will continue to be distorted if CMS proceeds with its proposal to include a revised BAPP measure for 2020 Stars, assess a data integrity penalty reduction to 1 Star based upon audit findings for appeals and MTM measures and finally, create multiple new Star measures informed primarily by audit findings, such as the Formulary Administration Analysis measure and new BAPP measures informed by the industry wide Timeliness Audits.

The purpose, intent and design of Medicare Advantage and Part D program audits is very different from the Star Ratings System. Program audits are an important tool used by CMS to monitor plan compliance with a series of regulatory requirements. However, these audits are qualitative assessments of Medicare Advantage plan and Part D sponsor processes and protocols, and may result in negative findings based on a sample of select individual cases in which CMS determines plan operations are not entirely in compliance with specific program requirements. Many of the audits used to inform Star Ratings are new, such as the MTM pilot audit and the Industry Timeliness studies. Additionally, not every plan is audited each year. Conversely, the Star Ratings System uses representative statistical samples from a variety of data sources to measure and compare clinical quality and beneficiary outcomes in one contract's beneficiary population with the beneficiary populations of other contracts.

Lower Star Ratings due to audit findings can impact beneficiaries by reducing additional benefits offered by plans or increasing cost sharing requirements. Additionally, the inclusion of audit findings and enforcement actions within Star Ratings may distort the beneficiaries' ability to evaluate plan performance. The impact to beneficiaries is widespread. In 2017 Stars, there were 2.2M beneficiaries enrolled in a 3.5 Star contract that had achieved 4+ Stars in 2016 Stars but was penalized in 2017 Stars for audit findings or enforcement actions. Overall in 2017 Stars, 68% percent of Medicare Advantage and Prescription Drug Plan beneficiaries were enrolled in plans with Star Ratings that were negatively impacted by audit findings or enforcement actions.

By incorporating audit findings into the Star Ratings System, CMS levies penalties that duplicate compliance actions for the same violation. Further, audit and compliance actions can impact Star Ratings and payment long after a plan has resolved an issue, due to the lag in how Star Ratings affect payment. Since not every plan is audited each year and the scope of audits conducted varies, there is an inherent bias in the collection of plan performance data. Finally, the Stars penalties and measures informed by audit findings are not representative of plan overall quality performance. For example, assessing data integrity penalties for an entire data set based on program audit findings or other reviews, which do not have a required minimum number of cases for reliable extrapolation, can lead to an erroneous conclusion. As CMS increases its frequency of audit and expands the scope of audits within the Star Ratings, Medicare Advantage

organizations and Part D plan sponsors will face increased likelihood of Star Ratings penalties. Star Rating penalties may result in less than 4 Star performance for plans that would otherwise receive high quality performance of 4 Stars or greater. Performance of less than 4 Stars would compromise the Medicare Advantage plan's funding through the Quality Bonus Payment (QBP).

CVS Health acknowledges CMS's authority to oversee the MA and Part D programs as well as to monitor required competencies and compliance with specified regulatory requirements. Upon detecting any deficiencies, corrective action is appropriate and warranted to ensure contractual obligations are met. To that end, administrative remediation needs to align with the magnitude of impact and degree of the error detected as well as its overall impact on the service and care delivered to the member. However, we remain concerned that the overall methodology and goals of the audits program and associated penalties do not align with the key principles outlined for the Star Ratings Program, especially if the results of such audits and CMPs are used as one of the data sources for measuring performance as reflected in the Star/Display measures, which are in turn a proxy for the level of service and care delivered to members.

Measure D06: Beneficiary Access and Performance Problems (BAPP)

CVS Health is supportive of moving BAPP measure to the Display page for 2019 Star Ratings and furthermore recommends retiring it from the Star Ratings System altogether.

Specific concerns around data sources for the BAPP measure include:

1. Audits do not have any demonstrated relationship with quality outcomes. The audits performed through the year test for regulatory compliance and alignment with current guidelines. Additionally, audits are based on samples that are specifically targeted to highlight the adverse impacts to encourage process improvement efforts and/or detect compliance failures not determine quality improvement initiatives.

2. The goal, method, and types of audits vary widely and can result in unequal and inconsistent impacts as to outcome and potential remediation protocol. Additionally, the BAPP measure methodology does not account for the audit/review lifecycle of plans, since not all plans are audited during a given review period.

3. Audit outcomes demonstrate a high degree of variability due to inconsistencies in auditor interpretations of regulations by an individual auditor. For example, in 2016, a CMS auditor provided a clarification of guidance by CMS explaining that a new beneficiary with a Nov 1 or Dec 1 effective date should be considered as both a new member and a renewing member for a transition supply in those months where the periods overlap. Prior to this, CVS Health had participated in multiple CMS audits where previous auditors had not made this clarification and found no issue with our systems and processes. The high degree of variability in auditor assessments demonstrated through this example substantiates that plans receiving different citations based upon the discretion of the individual auditor or the point in time at which they are audited.

Display Measure: Formulary Administration Analysis (FAA):

CVS Health strongly opposes the creation of new Star Rating measures tied to audit performance, such as the Formulary Administration Analysis (FAA) measure tied to collection of data from plan sponsors using CMS audit protocols.

For the FAA measure, our specific concerns include:

1. From our experience, CMS does not utilize a random sample of all rejected claims during the audit period to determine if the claim adjudicated correctly based upon the submitted approved formulary. Instead, CMS "targets" rejected claims that are inconsistent with the approved formulary. Since only a targeted sample of claims is incorporated into the analysis, it is inappropriate to reach conclusions regarding overall plan performance using audit results based upon examining a non-representative sample of claims already targeted as having potential compliance issues.
2. Contracts that have individual plans as well as Employer Group Waiver Plan (EGWP) plans are being sampled and evaluated multiple times. For example, we support a plan sponsor which was evaluated 25 times within one audit. However, another plan sponsor with only one individual plan might only be evaluated once. It would therefore be inequitable to compare one sponsor's results to another's due to the potentially vastly dissimilar levels of plan evaluation.
3. We have observed that the timing of the audit can vary, with long time lags between the initial audit and the findings. While in previous years the process has begun in June or July, in 2016 the audit did not start until September. Audit findings are reported approximately one year following the audit, which represents a significant lag from the initial audit. The goal of providing beneficiaries with relevant measures of plan performance is not achieved with this timeline of FAA activities.

Finally, as expressed through this response, Quality measurement based upon audit results is non-representative and arbitrary. Any new Star Ratings measure should use representative statistical samples from a variety of comparable data sources that primarily focus on measures of clinical quality and beneficiary's health outcomes designed to reflect the broad experience of plan enrollees.

Data Integrity:

CVS Health supports the concept of a scaled reduction, however, CVS Health remains opposed to the range of data sources, including audits, that CMS proposes to use to assess data integrity and the relative opaqueness of how audit results, outside of the Timeliness Monitoring Study, are used to inform data integrity issues. Assuming that data is inaccurate based on program audit findings or other reviews, which do not have a required minimum number of cases for reliable extrapolation, can lead to erroneous conclusions. We remain concerned with the lack of data-driven methodology used to determine data integrity issues. We recommend that CMS consider developing a data driven, streamlined approach that does not utilize audit data to assess a plan's data integrity. We ask that CMS provide additional information on the timeline/calendar for plans to be provided with information on scaled reductions, including simulations using retrospective data to gain insights into impact of this method.

High and Low Performing Icons:

CVS Health supports visual icons reflective of plans' Star Ratings performance on the Medicare Plan Finder website to aid beneficiaries with their choice of a high quality Medicare plan. However, we recommend that CMS remove the existing links between Star Ratings and audit results and enforcement actions by creating a separate icon to provide beneficiaries with visibility into a contract's audit performance.

CVS Health acknowledges the need to provide beneficiaries with insight into a plan's audit findings, but firmly believes this insight needs to be accomplished outside of the Star Ratings program to achieve CMS' stated goal of transparency to beneficiaries. It is unrealistic to expect beneficiaries to translate an overall Star Rating measure displayed on Plan Finder into a differentiated understanding of the plan's performance on quality measures and the plan's performance on audits or enforcement action. CMS has the opportunity to share information on audit scores and CMPs on the Medicare Plan Finder (MPF) website, which is a more appropriate, comprehensible way to communicate such information to beneficiaries. CVS Health would value the opportunity to work with CMS to determine the most transparent method to communicate audit scores, CMPs and sanctions to beneficiaries more broadly and publicly.

Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.

CVS Health is supportive of the evaluation of outcome-based measures for the Star Ratings Program that would encourage adoption of new technology by our members and providers to improve quality of care and health outcomes. We urge CMS to consider the following guiding principles as part of this evaluation:

1. Measures introduced to the Medicare Star Ratings Program should be under the control of the plan to influence. For example, PDPs do not have contractual relationships with prescribers, so while they may invest in developing new ePrescribing capabilities to improve quality of care, they have very little ability to influence the adoption of that technology by prescribers. Additionally, technologies that require beneficiary adoption need to consider demographic and geographic variations by plan since willingness or ability to adopt will vary by age, socio-economic status, access, etc.
2. Measures introduced to Medicare Star Ratings should be in alignment with measures used in government quality programs for other stakeholders in the patient's care, such as the telehealth measures designed for the MIPS/MACRA program. Aligning expectations and incentives across stakeholders is critical to facilitate adoption of new technologies.
3. Measures should focus on technologies that have evidence to support improved health outcomes. For example, the National Quality Forum (NQF) public report, "Telehealth Framework to Support Measure Development 2016-2017", narrowed 4 areas of care domain that will benefit from the telemedicine (i.e., Access to Care, Financial Impact/Cost, Experience and Effectiveness) as well as clinical areas (e.g., care coordination, chronic conditions, and behavioral health) that demonstrate positive impact

of telemedicine. NQF is now evaluating how the measure development framework developed can be applied and integrated to telemedicine situations and areas across the country that leverage telemedicine.

4. Measures should be outcomes vs. process based to ensure that CMS achieves its goal of improving quality as a result of adoption. The measure example provided by CMS of % of beneficiaries enrolled through online channels is of concern as this does not effectively measure the quality or improved outcome, and presents a high level of risk for plans to "check the box" without improving experience or health status.

CVS Health would appreciate the opportunity to partner with CMS and measure stewards such as PQA on developing measures related to the use of pharmacy related technologies, for example e-prescribing and e-prior authorization (ePA).

Contract Ratings:

CVS Health appreciates the willingness of CMS to consider separate rating systems for various contract characteristics, such as separate ratings for new contracts; or separate ratings at the plan benefit package (PBP) level or at the parent organization level for select Star measures. The Quality Ratings System should fairly assess performance considering unique characteristics of demographics, markets, and contract types assessed. Additionally, the Quality Ratings System should facilitate meaningful benchmarking of Medicare contracts (and plans) in order for beneficiaries to reliably choose a plan based upon quality of care provided.

1) PBP Level Reporting/Ratings

CVS Health has concerns with the administrative burden and decreased reliability that developing separate ratings systems at the PBP level would introduce. The additional administrative resources required could take away from the more important focus on improved quality. Additionally, variations in PBP performance are likely to result from differences in membership demographics and covered benefits, rather than from true differences in quality performance. As a result, plan level quality reporting would not better reflect the quality of care provided to enrollees in that plan.

CVS Health opposes implementing the separate ratings system at PBP and/or Parent Organization level; and instead recommends that CMS adopt robust risk adjustment methods, such as the method proposed by PQA, at the measure level to account for various factors that can influence plan performance, such as geography, age, socio-economic status; instead of creating multiple ratings systems.

2) Separate Ratings for New Contracts

CVS Health acknowledges that quality ratings for new contracts may be a reflection of the membership attracted to the plan as opposed to the quality of the plan's services and ability to influence outcomes. However, CVS Health has concern that separate ratings or standards for new contracts could create a loophole for plans to game the system. For example, a parent organization could create a new contract and move lives from a low performing contract into the new contract to avoid penalty. CVS Health requests that CMS provides the retrospective data simulations for the proposed scenarios for past three years to gain insights into impact of

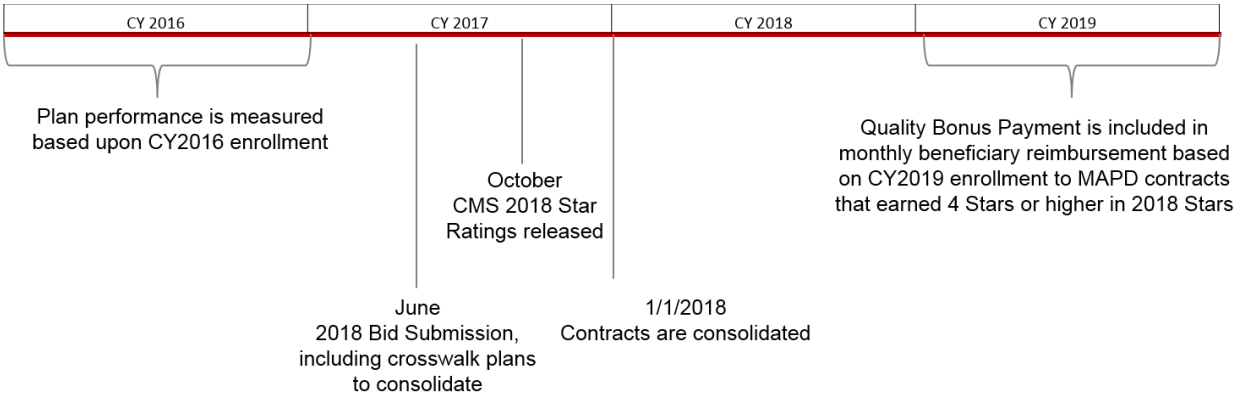
separate ratings system demonstration (demo) for new contracts by new MAO/established MAOs.

Contract Consolidations:

CVS Health is supportive of CMS' efforts to evaluate alternative approaches to assigning contract-level Star Ratings in the case of contract consolidations. However, we are concerned that CMS' proposed weighted average approach is not applicable across consolidation scenarios and introduces unnecessary complexity into the Ratings Program. Instead, we recommend an alternative approach to assign Star Ratings and award Quality Bonus Payment (QBP) for a contract based upon the performance that contract achieved on lives enrolled in the contract during the measurement period.

Currently, CMS awards the QBP to MAPD contracts that earn a rating equivalent or greater than 4 Stars. The QBP is awarded to the high performing contract as a per member per month reimbursement based upon lives enrolled during the QBP payout period, which lags the Stars measurement period by two years.

Example: 2018 Stars Timeline for Measurement, Rating and QBP Payment



Due to the substantial lag between QBP payout period and Star Ratings measurement period, the QBP payment does not necessarily align to the enrollment that the contract managed during the measurement period. CMS notes that in contract consolidations following novations there has been a continued increase in the number of enrollees being moved from lower Star Rating contracts that do not receive quality bonus payments (QBPs) to higher Star Rating contracts that do receive a QBP. Moving lives into higher rated contracts increases the size of the QBPs that are made to MAOs due to the increased enrollment in the higher rated, surviving contract during the QBP payout period. CVS Health shares CMS' concern that this practice results in masking low quality plans under higher rated surviving contracts; and falsely rewarding bonus payments on lives the contract did not influence during the measurement period.

To address this loophole of increasing bonus payments through contract consolidation, CMS proposes an alternative method to assign the Star Ratings based on an enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) for two years following

consolidation. This is a change from CMS' current practice of assigning the rating to the surviving contract without regard to the consolidation that occurred following the Stars measurement period.

CVS Health believes that it is imperative that the alternative approach that CMS designs should be equitable to different consolidation scenarios. The first scenario to consider is an elective consolidation, in which the contracts being consolidated were owned by the same parent organization during the Stars measurement period and the parent organization elects to consolidate the contracts following the measurement period. A second scenario to consider is a non-elective consolidation, in which the contracts being consolidated were owned by different parent organizations during the measurement period; and the acquiring parent organization is required to consolidate the contracts by the end of the transition period specified in 42 CFR 423.272(b)(3)(ii) because it cannot meet the meaningful difference standard with respect to multiple bids and to avoid a determination of involuntary non-renewal of a contract.

CVS Health does not believe that the weighted average method proposed by CMS would be appropriate to apply to the second scenario of a non-elective consolidation following acquisition of a new contract. In the second scenario, the acquiring parent organization did not have ability to influence the performance of the acquired contract during the Star Ratings measurement period because the acquired contract was not yet under its purview. With the proposed weighted average approach, if the acquired contract had superior Star Ratings performance, this could falsely inflate the ratings of the surviving contract. Alternatively, if the acquired contract had lower Star Ratings performance, it would falsely mask the high performance the surviving contract achieved during the measurement period. This would be misleading to beneficiaries, and inequitable to the contract.

CVS Health is also concerned that the weighted average approach introduces significant complexity and reporting burden based upon the multiple considerations for calculating weighted average performance across differing measures.

CVS Health urges CMS to consider alternative methods; and more specifically, recommends that CMS apply the following guiding principles for any novel approach to assigning Star Ratings and awarding Quality Bonus Payments following consolidation:

1. The method should result in an accurate and equitable reflection of the surviving contract's performance based on contract's ability to influence performance during the Stars measurement period.
2. The method should be applicable across consolidation scenarios
3. The method should be simple to implement and limit any incremental administrative burden.

To maintain the fairness and transparency of the Star ratings system and deter contract consolidation for purely financial gains, CMS could consider following alternative approaches that address the root cause of this issue. At its core, the potential for gaming QBP payments through consolidation results from the substantial lag between QBP payout period and Star Ratings measurement period. As a result, the QBP payment does not necessarily align to the

enrollment that the contract managed and therefore the performance the contract influenced during the measurement period.

To address this core issue, CMS should consider:

1. Continuing current practice of assigning Star Ratings to surviving contract based upon the performance achieved for members enrolled during the measurement period.
2. Awarding QBP to high performing surviving contracts based upon the average enrollment during the measurement period; not the enrollment during the QBP payout period.

In addition, CMS should expedite the payout of QBPs to the calendar year following the Ratings release for all contracts regardless of consolidation scenarios to minimize the likelihood of changes in contract membership, which could influence the QBP.

Measure-Level Star Ratings - Cut Point Analysis:

The CMS MA and Part D Star Ratings System is designed to provide information to the beneficiary that is a true reflection of the plan's quality and enrollee experience and to employ methodologies that minimizes risk of misclassification. The assignment of Star measure thresholds is the most fundamental method to determine a contract's overall Star Ratings and to differentiate industry performance. CMS proposes to continue to determine cut points by applying either clustering or a relative distribution and significance testing methodology and proposes to codify this policy. CMS indicates that it is considering methodologies that would minimize year-to-year changes in the cut points by setting the cut points so they are a moving average of the cut points from the two or three most recent years or setting caps on the degree to which a measure cut point could change from one year to the next.

CVS Health has significant concerns that the current clustering method to assign Star measure threshold cutpoint misclassifies industry performance, and as a result undermines the integrity of the Ratings. CVS Health strongly recommends that CMS re-evaluate and address the flaws with the current methodology prior to the 2019 Star Ratings release in October 2018.

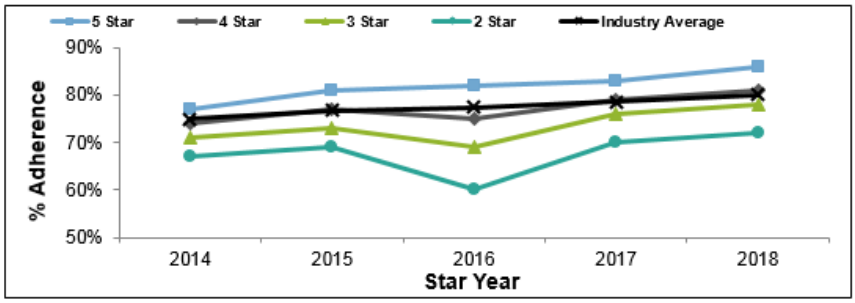
In summary, the following observations of industry performance resulting from the clustering method are in direct conflict with the CMS Guiding Principles for the Star Ratings.

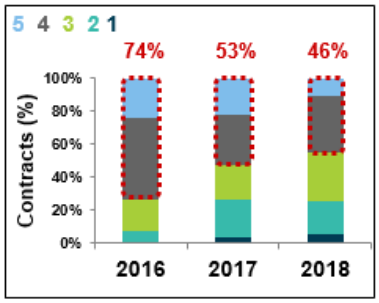
CMS Star Ratings Guiding Principles	Observations
Ratings are stable over time.	Across PDP and MAPD Star measures, thresholds often move independently of industry performance. While the industry demonstrates consistent annual improvement, thresholds increase and decrease at a different rate.
Ratings treat contracts fairly and equally.	Outlier contracts, which tend to have low enrollment, have the ability to establish the 5- or 2- star thresholds due to highly differentiated levels of high or low performance. The performance of these contracts is often volatile and not sustained over time. Contract characteristics, such as enrollment and LIS membership, are strongly correlated to Stars performance across many measures.
Improvement on measures is under the control of the health plan.	Many contracts demonstrate consistent Y-Y metric improvements, but drop a Star level. Conversely, in some measures, contracts whose metric performance declined Y-Y are rewarded by improving by at least a Star level.
Utility of ratings is considered for a wide range of purposes, including driving quality improvement for plans and providers.	In some measures, there is lack of differentiation in plan performance with > 90% of the industry earning high performance. A lack of differentiation in performance can mask low and/or declining performance, falsely rewarding almost every contract with 4+ Stars. Instability in thresholds results from outlier contracts with volatile, unstable performance, and can penalize contracts with consistent improvement. These hinder ability to establish improvement goals to improve Stars.

We have detailed two case studies below to illustrate how Star measure thresholds are not representative of industry performance trends and can misclassify contract performance. Cut points are easily influenced by outlier contracts, typically with <5k members, who demonstrate volatile, unsustainable changes in performance.

Case Study 1: MAPD D11: Adherence Diabetes

The line graph (to the left) below represents a YoY trend of cut points from 2014 Stars through 2018 Stars with industry performance during the same time represented as black solid line. The bar graph (on the right) represents the contract distribution across all star levels for MA-PD contract types for last three Star Years (SY) (i.e., 2016 Stars through 2018 Stars).





While the industry has maintained a consistent rate of improvement for the last three Star Ratings periods, Star level cut points have increased and decreased at a noticeably different rate than industry improvement.

For example, in 2016 Stars, the star cut points decreased (got easier) by 9% for 2- Stars, 6% for 3-stars and 4% for 4- Stars, despite the industry improving by 0.6%

Why did thresholds decrease while industry improved?

- A single contract with 1,714 enrolled members, H8266, achieved 23% for Diabetes Adherence, and established the 2- Star threshold. This caused a ripple effect decreasing other thresholds.

What was the impact?

- A sharp increase in contracts achieving 4+ Star rating, from 56% in 2015SY to 74% in 2016SY, primarily driven by the reduction in the threshold due to the low performing outlier.
- When the thresholds normalized in 2017 Star Ratings, proportion of contracts achieving 4+ Stars normalized to 53% of contracts.

In 2018 Stars, the star thresholds increased by 3% for 5- stars, 2% for 2-, 3- and 4- Stars nearly 2x the rate of industry improvement of 1.4%.

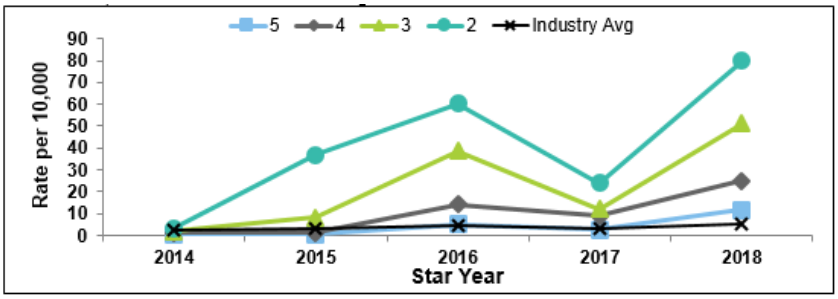
Why did thresholds increase at greater rate than industry improvement?

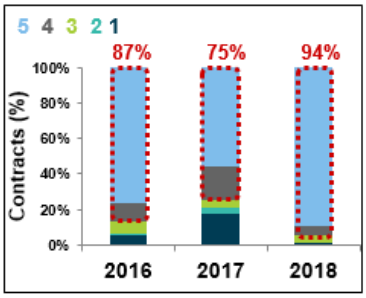
- In 2018 Stars, the 5-Star thresholds increase by 3% vs. industry improvement of 1.4% was highly influenced by a single contract (H2417) with 468 beneficiaries that achieved 98%. From 2016 to 2017 Stars, this contract achieved 90% and did not demonstrate any improvement.

What was the impact?

- 28 contracts serving a total of 2.7M beneficiaries achieved 1-2% year-year improvement from 2017, but received a lower Star rating for 2018.

Case Study 2: MAPD D02: Appeals Autoforward





There is lack of differentiation in plan performance, with >90% of the industry earning high Stars performance. However, this masks low and/or declining performance and falsely classifies nearly every contract as high performing.

For example, in 2018 Stars, the industry average performance got worse (i.e., increased) by 2.4, while proportion of contracts achieving 4+ Stars increased from 75% to 94%, with 89% of contracts achieving 5 Stars for 2018 Stars when compared to 2017 Stars.

Why did >90% of industry achieve high performance?

- In 2018 Stars, 3 outlier contracts (<1% of industry) received an Autoforward metric >51: H9808 (12K lives), H7115 (4k lives) and H2968 (2k lives). This made thresholds

significantly easier, increasing the proportion of contracts who achieved high performance.

What is the impact?

- As a result, 24 contracts (14% of MAPD contracts who received a rating on this measure) whose metric performance got worse from 2017 to 2018SY were rewarded by improving by at least a Star level.
- 16 contracts (9% of MAPD contracts who received a rating on this measure) had a decrease in metric performance of ≥ 5, either retained or increased a Star level from 2017 to 2018SY.
- In total, 338 contracts earned 5 Star performance in 2018 Stars with a metric <11.6. Such broad classification of 5 Star performance did not differentiate the 96 contracts, approximately 25% of the industry, who earned perfect performance (i.e., a metric of 0.0).

The case studies highlight two examples of how the current clustering method can misclassify industry performance; however, other examples exist for Part C measures, such as C01: Breast Cancer Screening, C07: Adult BMI Assessment, C33: Reviewing Appeals Decisions; and for Part D measures, such as PDP D13: Adherence Statin, D04: Complaints, and D05: Members Choosing to Leave the Plan.

In summary, we recommend CMS consider the following to ensure the assignment of thresholds accurately reflects industry performance:

1) Reduce the Impact of Outliers

The Clustering Method with Ward's Minimum Variance has a known susceptibility to outlier performance. To account for this, CMS could consider an alternative method or introduce a modification within the current method, for example trimming of contracts at the 99th and 1st percentile prior to the running of the cluster for assignment of cutpoints to limit the influence of potential outliers. The outlier contracts could still receive a star rating, but would not be included in the calculation used to establish the cutpoints.

2) Align Star performance to Industry Average trends

Per CMS definition, the 3 Star Rating is intended to indicate average performance. However, there is no consideration for the industry average performance trends when assigning Star cutpoints. CMS could consider alternative methods that anchor the 3 Star cutpoint to industry average, excluding performance outliers, and then differentiate high and low performance from there.

Furthermore, CVS Health is not supportive of the alternative methods CMS highlights in the NPRM document.

1) Moving Average:

CMS indicates that it is considering methodologies that would minimize year-to-year changes in the cut points by setting the cut points so they are a moving average of the cut points from the two or three most recent years. We have concern regarding the longevity of such a methodology. As time progresses, thresholds become less of an indication of industry performance and more of a historical implication of performance. Additionally,

the current thresholds are not representative of industry performance so any future threshold assignment should not be based upon existing thresholds.

2) Cap on degree to which a measure cut point can change
CMS also indicates that it is considering methodologies to set caps on the degree to which a measure cut point could change from one year to the next. Although this could address some of the volatility experienced within the current methodology, it may mask true changes in industry performance and fail to differentiate high or low performance.

Adding, Updating, and Removing Measures:

CVS Health supports the CMS proposal to formularize the rules to govern the addition, update and removal of measures, and to reduce the constant changes to the Star Ratings measures.

CVS Health supports the CMS proposal to keep measures on the display page for at least two years and supports the acknowledgement that CMS would keep a new measure on the display page for a longer period of time if CMS finds there are reliability or validity issues with the measure. Further, CVS Health agrees with CMS' proposal that will not allow a measure to be added when the measurement period has passed.

CMS indicates that it will continue to analyze measures to determine if measure scores are "topped out", showing high performance across all contracts decreasing the variability across contracts, or if measures have low reliability. CVS Health requests further definition of the criteria used to determine if a measure is topped out. Our analysis of Part D measure performance has uncovered several instances where measures appear topped out as >80% of the industry has achieved >4 Star performance, but upon further review there is significant variation in metric performance. The assignment of high Stars performance masks differences in metric level performance. In this instance, the measure could be falsely classified as topped out while in fact the industry has considerable opportunity to improve. We recommend that CMS reviews the underlying methodology to assign annual cut points in addition to providing more specific guidelines for assessing is a measure is topped out.

CVS Health supports CMS in its proposal to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period. CVS Health asks that CMS provide more insight than is contained in the proposed rule to ensure the criteria are objective and fair. CVS Health has raised concerns in the past about changes that CMS staff determined to be non-substantive when the changes were in fact substantive. For example, last year CMS proposed changes to the MPF Price Accuracy measure to include the frequency as well as the magnitude of pricing differences. This fundamentally changed the measure calculation by introducing a second criteria for plan performance. Prior to reaching any decision regarding substantive or non-substantive changes, CMS should publish the proposed technical specifications for the methods along with simulations of contract and industry performance; and provide time for comment from the industry to determine whether a measure change is substantive or non-substantive. Further, we recommend that CMS establish a process for any challenges raised as to whether a change is substantive or non-substantive.

Hierarchical Structure of the Ratings:

CVS Health is supportive of the current policy as it relates to the Hierarchical Structure of the Star Ratings Program.

Domain Star Ratings:

CVS Health is supportive of the current policy as it relates to the Domain Star Ratings of the Star Ratings Program.

Part C and Part D Summary Ratings:

CVS Health is supportive of the current policy as it relates to the Part C and Part D Summary Ratings of the Star Ratings Program.

Overall Ratings:

CVS Health is supportive of the current policy as it relates to the Overall Ratings of the Star Ratings Program.

Reward Factor (formerly Integration or *i* Factor):

CVS Health is supportive of including the reward factor adjustment in the overall Star Ratings score to recognize contracts that maintain high performance consistently, in a YoY performance trending. The Reward Factor, an adjustment introduced in the Star Ratings Program since 2009, is used to incentivize plans to achieve stable and consistent high performance year to year. However, we are concerned that the current methodology of calculating the reward factor does not consistently award contracts who maintain high performance and demonstrate incremental improvement at measure-level. For example, it is possible for a contract to maintain a 4 Star Rating and 4 Star performance on the Quality Improvement measure, and not receive the Reward Factor. The current reward factor method utilizes a plan's Summary Rating (Mean) and the variability of Star (not metric) performance across all measures for specific Star Ratings component. As a result, the assignment of the Reward Factor is highly influenced by the known flaws in the assignment of Star measure cut-points. Furthermore, we request that CMS publishes the annual list of the Reward Factor recipients at contract level similar to the Categorical Adjustment Index (CAI) adjustment in spirit of maintaining the fairness and transparency of the Star Ratings System.

Categorical Adjustment Index (CAI):

We appreciate CMS' continued focus on risk adjustment for factors that impact a contract's performance on the Medicare Star measures. Health outcomes can be influenced by many factors other than the healthcare services received, including patient-related factors such as existing clinical conditions and sociodemographic status (SDS). SDS refers to a variety of socioeconomic (e.g., income, education, occupation) and demographic factors (e.g., age, race, ethnicity, primary

language). To avoid incorrect conclusions or inferences about the quality of care delivered, it is important to control for these factors.

CMS introduced the Categorical Adjustment Index (CAI) as an interim methodology to adjust for Low Income Subsidy (LIS) and Disability status amongst a plan's membership. Prior to codifying the current interim method, CVS Health urges CMS to improve the appropriateness of the adjustment through the modifications detailed below. In parallel, CMS should accelerate the adoption of measure level risk adjustment methods proposed by national measure stewards, such as PQA.

The appropriateness of the current CAI adjustment is questionable. For example, there are instances where the CAI adjustment has an increasingly negative impact on a contract's performance as the contract increases the % of LIS beneficiaries it serves. For example, a PDP contract's % LIS membership increased from 15% to 28% from 2017 to 2018 Stars. The same contract's CAI adjustment had an increasingly negative impact, growing from -0.022 in 2017 Stars to -0.190 in 2018 Stars, which did not reflect the impact of increased LIS burden on the contract during that time. During the same time, the overall rating of the contract slipped from 3.5 Stars for 2017 Stars to 2.5 Stars for 2018 Stars with negative CAI playing a role in the final score awarded.

To improve the appropriateness of the adjustment and account for the DE/LIS burden carried by contracts, we recommend the following modifications to the interim methodology:

1. **Expand the number of Star Rating measures included in the adjustment model.** For each measure, quality performance evolves each year and can improve or decline. If limited measures are included, the adjustment approach may miss important disparities that, in aggregate, could considerably influence a plan's performance. One of the decision criteria that CMS used to determine which measures were selected for adjustment was "a median absolute difference between LIS/DE and non-LIS/DE beneficiaries of 5% or more." We request clarification around why the 5% disparity was chosen, as it appears to be arbitrary. Any difference noticed between LIS/DE and non-LIS/DE beneficiaries should be included in the risk adjustment in order to uncover critical disparities in performance. While we are pleased that CMS has included an additional measures in the Categorical Adjustment Index (CAI); namely, MTM CMR Completion rate for the Part D Rating adjustment, we do not believe this is an adequate effort to account for the LIS/DE impact on contracts.

   PQA recently published a summary recommendations in a white paper titled, "Sociodemographic Risk Adjustment of PQA Proportion of Days Covered (PDC) Measures Used in the CMS Medicare Part D Star Ratings Program" concerning the SES adjustment methods they will introduce for all three medication adherence measures, Diabetes, RASA and Statin. PQA found that risk adjustment was appropriate for all three PDC adherence measures. Currently, the CAI does not include all three adherence measures in its adjustment calculation. PQA's recommendations reinforces that the CAI adjustment needs to be informed by an expanded set of measures.

2. **Enhance the categorization approach.**
   While the MAPD categories increased year-over-year from 50 categories of LIS and Disability to 60 categories, PDP categories remain at 16 categories. By creating more categories for plan groupings, risk adjustment will more accurately account for the range of plan and patient characteristics and improve the similarity of plans that are grouped together. Furthermore, while the CAI had an overall minimal impact on contract Star Ratings performance for the 2017 Star Ratings, it had a strikingly different impact on MAPD and PDP plans with similar LIS and Disability characteristics. PDP plans experienced a highly negative impact from the CAI as compared to MAPD plans.

3. **Incorporate other factors that are well-known as predictors of medication adherence and other Star Rating quality outcomes.**
   At a minimum, two predictors, age and gender, should be included in the risk adjustment approach. Age and gender are both readily available variables and, given their association with adherence and other quality measures, they should be incorporated into the adjustment model. CMS has taken this approach in the CAHPS adjustment as these factors are a strong indicator of outcomes.

We encourage CMS to adopt measure level risk adjustment methods from measure developers such as the NCQA and the PQA to more specifically address measure-level disparities. We request additional information regarding how measure-level adjustment may be incorporated into CMS's current risk adjustment approach, the CAI, if at all. Additionally, we support the three part "Strategy for Accounting for Social Risk in Medicare's Value-Based Purchasing Programs" identified by the Office of the Assistance Secretary for Planning and Evaluation (ASPE) outlined in its Report to Congress: "Measuring and reporting quality for beneficiaries with social risk factors, setting high, fair quality standards for all beneficiaries, and the provision of targeted rewards and supports for better outcomes for beneficiaries with social risk factors, may help ensure that all Medicare beneficiaries can achieve the best health outcomes possible." We are also looking forward to the additional report from ASPE that is anticipated to propose the adjustment approaches at the measure-level to account for social risk factors associated health disparities.

Finally, tracking down and/or finding contact information for LIS members continues to be a challenge for plans serving this population. Members who are auto-assigned have far less contact information upon enrollment than members who self-enroll. The lack of contact information inhibits a contract's ability to outreach and address member challenges, influence member behavior and improve clinical outcomes. We seek support from CMS on new and innovative ways to ensure contact information provided by CMS is not a barrier to improving beneficiary health care while ensuring member privacy as required by HIPAA (Health Insurance Portability and Accountability Act of 1996).

Plan Review of Star Ratings:

CVS Health supports the current plan preview process as well as the quarterly data validation reviews for complaints and appeals measures. CMS holds plans accountable to monitor and improve performance on an ongoing basis, and therefore it is imperative that it provide the

necessary data for plans to do so in a timely and accurate manner. Advance opportunity to validate internal monitoring of Star measure performance ensures alignment with CMS methods and facilitates improvement efforts.

We urge CMS to consider developing similar validation processes for the Stars adherence metrics. Given the complexity of the patient safety measures, plans need a way to validate internal reporting and monitor industry average performance to drive quality improvement efforts throughout the measurement period. In an effort to aid plan sponsors with rigorous monitoring and oversight of adherence metrics, we specifically request that CMS consider the following recommendations:

a) CMS should implement more timely and frequent drug list updates and PDE edit updates to ensure reporting accuracy.
   - Today, Acumen reporting is only updated twice per year to reflect the updated PQA drug lists that are published in July (with NDCs released through May 31st) and February (with NDCs released through December 31st). The updates are integrated into the next reporting cycle. For 2018 plan year, this means that PQA drug list updates released in February will be integrated into the April Acumen Patient Safety reporting release, which is published at the end of April or early May 2018. This results in an effective delay of at least four months and at most nearly a year between the release of new NDCs and integration into Acumen Patient Safety reporting. The delay to integrate new drugs results in inaccuracies in reporting, which limits a plan's ability to monitor and influence performance and limits the ability to raise concerns in advance of Star Ratings Release.

b) Including Unadjusted Overall Adherence performance in regular Acumen reporting.
   - Current Acumen reporting only includes Overall Plan performance adjusted for CMS exclusion criteria of In-Patient Hospital Stays, Skilled Nursing Facility Stays, Hospice and ESRD. Visibility into the unadjusted overall adherence affords plans the opportunity to, (1) validate internal reporting vs. an external source on a regular basis, and (2) assess the impact of adjustment factors (overall) throughout the year.

c) Providing plans with visibility into the specific impacts of adjustment factors for inpatient hospital stays, SNF stays, hospice stays and ESRD on at least an annual basis.
   - Plan sponsors, and PDPs in particular, have limited visibility into member inpatient hospital stays, SNF stays, hospice stays and ESRD status.
   - This information would allow plans to independently assess the impact of adjustment factors on their population to ensure accuracy of internal monitoring and to better understand the health of their membership.

d) Providing plans with a validation dataset for the Stars adherence metrics that plans could run through their internal reporting processes to assess if they reach the same unadjusted PDC rate as Acumen.
   - CVS Health carefully monitors and incorporates annual changes in CMS reporting methodology into our internal methodology for SSIC. However, it is

difficult for us (and other plans) to assess if we have accurately reflected the CMS methodology since there is limited external information for us to compare against. It is very difficult to uncover systemic opportunities to improve internal monitoring through evaluation of discrepancies at the member level.

- We request that the validation dataset would be comprehensive of data needed to perform the PDC calculation (claims, eligibility, etc.) on a meaningful number of members (e.g., 20k). The data could be blinded (i.e., data do not have to pertain to actual members enrolled in the plan).
- CMS could reference the NCQA Measure Certification program as a best practice. This program was designed for organizations that develop, license, and sell HEDIS, P4P, or other quality-measure reporting software that calculate measures using administrative data sources. NCQA's Measure Certification program validates the integrity of the software code that produces measure results. NCQA creates unique sets of sample data or "test decks," for each measure, developed from randomly generated member-level test data. Test decks test denominator, numerator and exclusion logic. Plans process this test deck through their HEDIS or P4P measure code. NCQA then compares the plan's measure results to the expected results to determine if the code in the plan's software computes the measure correctly. Multiple test decks are available for each measure. Link: http://www.ncqa.org/hedis-quality-measurement/certified-survey-vendors-auditors-software-vendors/quality-measure-certification

e) Currently, Acumen only reports clinical "patient safety" measures. Reporting across other operational measures on a monthly basis would assist plans with continuous quality improvement.

f) Currently, Acumen reports industry type average to each plan (e.g., PDP average). Industry metric range would assist with threshold projections/analyses.

12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types.

Page(s): 56407-56411

CMS states that Part D sponsors have developed "standard terms and conditions" that in some cases have had the effect of circumventing the any willing pharmacy ("AWP") requirement and inappropriately excluding pharmacies from network participation. CMS states that this is a result of the development of preferred pharmacy networks in which certain pharmacies agree to additional or different terms from the standard terms and conditions.

CVS Health agrees that Part D plans should not be allowed to circumvent the AWP requirement, whether by declining to permit pharmacies to participate in their networks on the grounds that they do not meet the plan's definition of a pharmacy type for which it has developed standard terms and conditions, or by inappropriately waiving the standard terms and conditions for certain pharmacies. However, we are puzzled and concerned that CMS attributes the abuses of the AWP requirement to the development of preferred pharmacies. CMS provides no explanation for this

linkage, and the abuses cited by it are not only unrelated to the preferred pharmacy provision, but can all be addressed without making changes to the preferred pharmacy concept.

Since the inception of the Part D program, plans have been negotiating different terms and conditions for differently-situated subsets of the pharmacy network (e.g., rural pharmacies), and have been choosing whether to offer preferred pharmacies and, if so, which pharmacies to include as preferred. One example where CVS Health has negotiated and instituted different terms and conditions is for "rural pharmacies," taking into consideration the following:

- The geographical location of a pharmacy
- The higher acquisition costs incurred by a pharmacy situated in a remote and/or sparsely populated area and;
- The need to include that pharmacy location in the network to serve a remote member population and so meet convenient access standards.

In this case, whether the pharmacy is located in the Aleutian Islands off the coast of Alaska, a sparsely populated island in Hawaii, or a pharmacy located off the coast of North Carolina, CVS Health has taken into consideration the financial implications of acquiring drug inventory that requires additional transportation costs and associated costs of purchasing less volume (that can equal less lucrative discounts to these differently-situated pharmacies) in order to arrive at the appropriate negotiated contract rate(s) to provide access to these more remote member populations. The negotiated reimbursement rates— in these circumstances —may be less aggressive (i.e., higher) as compared to the rest of the network; however, it is a competitive, relevant rate for the differently- situated pharmacy location and the Medicare Part D members it serves, and strikes the right balance between ensuring convenient access while still negotiating a reasonable reimbursement rate in the circumstances.

At the time the Part D program was created in 2005, CMS took great pains to balance the AWP and preferred pharmacy requirements of the statute so as to provide "broad pharmacy access" while still giving Part D plans "appropriate contracting tools to lower costs."[1] CMS did this by building certain safeguards into the program to ensure broad pharmacy access for enrollees, such as requiring that pharmacy standard terms and conditions be "reasonable and relevant", that plans meet convenient access requirements, and that any variation in standard terms and conditions not discriminate against certain groups of enrollees. Together, these safeguards ensure that enrollees have access to broad pharmacy networks while still having the option to lower their drug costs by choosing preferred pharmacies.

One example of using the appropriate contract tools to lower plan costs is to utilize preferred pharmacies, especially in densely populated areas of the country where there also is heavy saturation of retail pharmacy locations, most often occurring in metropolitan but even in some micropolitan areas of the country. In this instance, not all retail pharmacies in a saturated area are needed to meet or exceed member access standards so negotiation leverage can be applied to help contain plan costs or allow for additional plan cost savings in some cases. This leverage

[1] See 70 Fed. Reg. at 4254 (*"[W]hen a statutory provision may reasonably be interpreted in two ways, we have an obligation to adopt the interpretation that gives full effect to competing provisions of the statute. We believe that our policy of permitting cost-sharing discounts for preferred pharmacies, as codified in § 423.120(a)(9), strikes an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs.")*

allows innovation and creativity in pricing and leads to a healthy competitive marketplace as pharmacies strive to improve efficiencies and cut unnecessary costs to remain competitive, cost effective and attractive in the contract negotiation process. In addition to using preferred pharmacies as a cost containment tool, CVS Health also utilizes other contracting strategies to contain costs and ensure appropriate access for its members consistent with the AWP requirement, such as:

- Contracting with groups of independent retail pharmacies through a Pharmacy Services Administration Organizations (PSAOs) for both a preferred and its broader standard (non-preferred) underlying network so that in the event some of the PSAO-affiliated pharmacies are not in agreement with the negotiated rates, they can choose not to contract through the , in which case they will receive t the standard reimbursement rate— which may be more acceptable and so allow them to remain in the network thereby avoiding member disruption;
- Negotiating to ensure a mix of different retail pharmacies—both chain and independent—within a preferred network so as to provide members with access to both local community pharmacies as well as national pharmacies within preferred pharmacy networks;
- Allowing high-performing pharmacies to gain entry to preferred networks based on their consistent high levels of performance metrics that are aligned with STAR ratings, thus ensuring that the plan members who are financially encouraged to use preferred pharmacies (e.g., differential copay/coinsurance plan designs) are served by consistently high-performing pharmacies.
- Varying standard terms and conditions as necessary to allow the inclusion of different or non-traditional retail pharmacy types in the network, such as physician dispensers and hospital pharmacies. This recognizes and addresses their differences through innovative and creative contracting solutions, rather than eliminating these pharmacies from the network because they are unable to comply with the current standard terms and conditions.

While we encourage CMS to address the concern that plans are inappropriately defining certain pharmacy types or services in a way that precludes certain pharmacies from being able to participate in their standard networks, we are concerned that CMS's linkage of these AWP abuses to preferred pharmacies may signal an intent to modify or re-interpret the AWP requirement in a manner that would upset the delicate balance so carefully struck in the final rule published on January 28, 2005 ("2005 final rule"), and would have the effect of eliminating or undermining the preferred pharmacy provision, such as by requiring that plans allow any willing pharmacy into their preferred networks. As CMS stated in the preamble to the 2005 final rule:

Ultimately…it is at Part D plans' discretion how they will establish pharmacy networks—including the offering of contracting terms and conditions that are different than standard contracting terms and conditions and the establishment of preferred pharmacies provided they meet our pharmacy access standards, non-discrimination provisions, and other applicable requirements under Part D."[2]

[2] 70 Fed. Reg. at 4249-4250

The main goal of a preferred pharmacy network is to allow Part D sponsors to negotiate deeper discounts with certain pharmacies in return for providing them with the opportunity to gain a greater share of Part D prescription volume through offering lower cost-sharing at these pharmacies. The success of this strategy depends on Part D sponsors having the flexibility to selectively solicit as preferred pharmacies those pharmacies that not only meet its performance standards and member access criteria, but that will be able to deliver their services at the most competitive reimbursement rates. If preferred pharmacy networks are open to any willing pharmacy, no pharmacy will have the incentive to offer deeper discounts since the plan will not be able to provide any assurance that the pharmacy will be able to make up for the lower pricing through increased prescription volume. This would effectively spell the end of preferred pharmacy networks in Part D, which have been and continue to be an unqualified success, both in terms of program savings and member popularity.[3]

This is the case since these plans are not only able to offer lower premiums without any sacrifice in quality, but put members in control by allowing them to choose to use either a preferred or non-preferred pharmacy. In light of this, there is no need for, and potentially significant harm in changing the way preferred networks are set up or operate, since they are achieving what Congress intended, namely, offering members the choice to pay lower cost sharing in return for utilizing a subset of network pharmacies through which Part D sponsors are able to drive greater cost savings without any sacrifice of quality. These preferred network offerings are similar to preferred network plans available in the commercial market. It is precisely this type of choice, offered in the commercial market, that Congress wanted to ensure is made available to Medicare members, and in this it succeeded admirably.

We strongly urge CMS to clarify that it does not intend to extend the AWP requirements to preferred pharmacy networks. Given the popularity of preferred pharmacy plan designs with members and the significant savings they produce, such a change would not only increase costs for both members and the Part D program, but would be contrary to the statute and Congressional intent.

CVS Health's position remains that the main objectives of a preferred cost sharing network are to negotiate the most competitive pricing with retail pharmacy providers and in exchange for deeper pricing discounts, to provide the pharmacy provider with the opportunity to gain a greater share of Part D enrollee prescription volume.

Requiring an "any willing provider" component for preferred cost-sharing networks:

1. Negates crucial price negotiation strategy to extract the most competitive rates from pharmacy providers;

[3] *See* Milliman, "The Impact of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2013," (Oct. 2013). Available at: http://www.pcmanet.org/images/stories/uploads/2013/milliman%20preferred%20pharmacy%20networks.pdf ("Preferred pharmacy network plans are estimated to reduce federal Medicare spending by approximately $870 million in 2014.Over the next ten years, preferred pharmacy network plans are estimated to reduce federal Medicare spending by $7.9 to $9.3 billion"). See also Adam Fein, Drug Channels (October 17, 2017 available at http://www.drugchannels.net/2017/10/exclusive-preferred-pharmacy-networks.html ("For 2018, 99% of Medicare Part D regional prescription drug plans (PDP) will have a preferred network. This figure exceeds those of the past four years. The three largest open network plans from 2017—CVS Health's SilverScript Choice and WellCare's Classic and Extra plans—have given up and will have preferred networks.").

2. Increases plan costs due to stripping the key differentiating element in a negotiation strategy; and
3. Defeats the ability to implement cost-saving incentives for Part D enrollees.

More importantly, it is CVS Health's belief that instituting AWP requirements for preferred cost-sharing networks yields the following outcome:

1. Promotes pharmacy complacency across the network that discourages differentiating high-performing pharmacies to remain invested in value-based models, and ultimately drives mediocrity and an overall leveling or drop in pharmacy performance;
2. Leads to a less competitive pricing environment and ultimately drives up CMS costs; and
3. Results in consequences that are counterintuitive to CMS' original intent.

Any Willing Pharmacy Required for All Pharmacy Business Models

CMS states that it is not appropriate for Part D plan sponsors to decline to permit a willing pharmacy to participate in a particular network on the grounds that it does not squarely fit into that pharmacy type, such as when a pharmacy has multiple lines of business and/or specialized services, e.g. specializes in certain drugs or diseases or provides home delivery service. It clarifies that, although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D plan sponsors must permit any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type (which CMS considers to be a "similarly situated" pharmacy) to participate in the network, even if the pharmacy does not operate exclusively as that type of pharmacy. It also states that that Part D sponsors must not exclude pharmacies from their retail pharmacy networks solely on the basis that the pharmacy specializes in certain drugs or diseases or provides home delivery service.

CVS Health appreciates CMS's confirmation that Part D sponsors may continue to tailor their standard terms and conditions for different types of pharmacies and/or special situations. It is essential for patient safety that pharmacies have the operational capability and clinical expertise to deliver the type of medications and services applicable to a particular type of pharmacy. This is consistent with CMS's specific requirement that long-term care pharmacies be able to meet additional "professional and service criteria" related to the long-term care setting. It is also essential that plans have the flexibility to vary their terms, including reimbursement terms, for certain subsets of pharmacies so that they are able participate in the plan's network. CMS has clearly recognized that different types of pharmacies may have different cost structures and impose different costs on Part D sponsors, and that Part D plans may take these into account in establishing their standard terms and conditions for each type of pharmacy. As CMS stated in the preamble to the 2005 final rule with respect to retail and mail pharmacies: *We clarify that a Part D plan could have standard terms and conditions for retail pharmacies and a second, separate set of standard terms and conditions for mail order pharmacies in light of those pharmacies' different characteristics. For example, a plan's contracting terms and conditions for mail-order pharmacies could reflect the full cost of adding another mail-order vendor, as well as the*

differential costs of strong data controls involved with having multiple network mail-order pharmacies.[4]

CVS Health also appreciates CMS confirming that pharmacies that specialize in dispensing specialty medications or medications for certain diseases should not be precluded from participating in a Part D sponsor's retail network solely because they provide home delivery of some or all of these medications. Nor should a pharmacy be excluded from participating in a retail pharmacy network merely because it operates additional business types/offers specialized services. We understand CMS to be saying, and we agree, that a pharmacy with multiple service types cannot be excluded from the network if they can meet the retail standard terms and conditions notwithstanding their additional services, though they can be asked to agree to additional terms and conditions reasonable and relevant to their other service lines.

However, we encourage CMS to make clear that its proposed definition of "similarly situated" pharmacies (namely, "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"), is not intended to limit the circumstance in which plans are permitted to vary their standard terms and conditions. Our confusion lies in the fact that, if plans are required to offer the same standard terms and conditions to all similarly situated pharmacies, and a similarly situated pharmacy is any pharmacy capable of meeting the plan's terms and conditions, CMS's definition of "similarly situated" is circular, and it is not clear on what basis a plan may vary its standard terms and conditions. The definition fails to recognize or accommodate the two situations in which plans are currently permitted to vary standard terms and conditions, namely, to accommodate certain pharmacies or subsets of pharmacies based on geographic access (e.g. rural or independent pharmacies), or based on the different characteristics of different types of pharmacies (e.g. retail, mail or specialty pharmacies).[5] As such, we are concerned that CMS's proposal could be interpreted as eliminating the ability of plans to vary their standard terms and conditions in these situations, thereby requiring that plans offer the same terms and conditions, including reimbursement rates, across the board to all pharmacies.

If this is CMS's intention, it would have profound negative implications for the Part D program, resulting in higher drug costs or limited pharmacy options for enrollees or some combination of both. For example, plans would no longer be permitted to offer higher (i.e., richer)

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[4] 70 Fed. Reg. at 4253

[5] 70 Fed. Reg. at 4254 *("However, it is unreasonable to assume—the any willing pharmacist requirement notwithstanding—that a Part D plan could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies (for example, rural and long-term care pharmacies). We clarify that standard terms and conditions particularly for payment terms may vary to accommodate geographic areas or types of pharmacies) and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. Thus, for example, provided Part D plans offer all mail-order pharmacies in a particular area with the same standard terms and conditions, they may offer separate standard terms and conditions to mail-order pharmacies*."). See also section 20.7 of Chapter 5 of the Part D Manual ("*CMS notes that Part D sponsors have the flexibility to vary the actual dispensing fee paid to pharmacies. For example, Part D sponsors may need to increase the dispensing fees paid to rural or long-term care pharmacies in order to obtain their participation in networks and meet the pharmacy access standards*.")

reimbursement rates to independent or rural pharmacies, but would have to offer the same reimbursement rates to all retail pharmacies, including major retail chains. This would have the effect of raising drug prices for members and the program as a whole. Alternately, a lower reimbursement rate offered to large pharmacy chains based on their economies of scale may not be acceptable to smaller pharmacies. While the convenient access standards would be a limiting factor that might require plans to offer slightly higher reimbursement rates, the result would still be a suboptimal network. There would be fewer smaller, rural and/or independent pharmacies and higher drug costs than could have been achieved by allowing plans to vary reimbursement rates as needed to achieve the network they seek for their enrollees at the lowest possible cost.[6] And while we agree that aggregate drug costs at preferred pharmacies should be lower than at non-preferred pharmacies, we do believe Part D sponsors should be allowed to take into account pharmacies that are not similarly situated. For example, there should be flexibility in allowing a preferred pharmacy in a remote location, such as rural Alaska, to receive higher reimbursement than a non-preferred pharmacy located in a non-rural area (i.e., in urban Los Angeles).

Finally, we note that such a policy, in addition to negatively affecting members and the Part D program as a whole, would violate the non-interference clause of the statute.[7] The non-interference clause prohibits CMS from interfering in negotiations between Part D plans and pharmacies, and is the key statutory provision designed to ensure that Part D remains a competitive, market-driven program. CMS has repeatedly acknowledged that this statutory provision prevents CMS from intervening in negotiations with pharmacies.[8] As CMS specifically stated in the preamble to the 2005 final rule: *As provided in section 1860D–11(i) of the Act, we have no authority to interfere with the negotiations between Part D plans and pharmacies and therefore cannot mandate that Part D plans negotiate the same, or similar, reimbursement rates with all pharmacies.*[9]

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[6] .It would also effectively eliminate the ability of plans to establish preferred pharmacy networks consistent with CMS requirements (i.e., aggregate drug costs at preferred pharmacies are lower than at non-preferred pharmacies). This cannot be achieved unless Part D plans are permitted to vary the reimbursement rates offered to these pharmacies. See, for example, Call Letter for CY2013 (April 1, 2013) at p.175 ("We are concerned because our initial results suggest that aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) may be higher in preferred networks than in non-preferred networks in some plans. Combined with lower cost sharing, we believe these higher unit costs may violate the requirement not to increase payments to such plans."). While we agree that aggregate drug costs at preferred pharmacies should be lower than at non-preferred pharmacies, Part D sponsors should still be allowed to take into account the different circumstances of different pharmacies, whether they are preferred or not. For example, there should be flexibility in allowing a preferred pharmacy in a remote location, such as rural Alaska, to receive higher reimbursement than a non-preferred pharmacy located in a non-rural area (i.e., in urban Los Angeles)

[7] See Section 1860D-11(i) of the Social Security Act states:
i*) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.*

[8] *See* 70 Fed. Reg. 4194, at 4236 (Jan. 2005) ("As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans") (discussing dispensing fees).

[9] *Id.* at 4255 (responding to requests that CMS set the same reimbursement rates for mail and retail). See also 70 Fed. Reg. at 4245 (As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans.") (Discussing dispensing fees); 70 Fed. Reg. at 4250 ("We believe that the type of market intervention requested by the commenter is contrary to the Congress's intent that we not interfere in the private negotiations between Part D plans and pharmacies.") (requesting that CMS require that Part D plans offer inner city and rural pharmacies the terms and conditions

Revise the Definition of Retail Pharmacy and Add a Definition of Mail-Order Pharmacy

CMS states that in order to eliminate confusion, it is proposing to define a 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 also proposes to revise the definition of "retail pharmacy" to include the requirement that the pharmacy be open to dispense prescription drugs to the walk-in general public and from which Part D enrollees could purchase a covered Part D drug at retail cost sharing. Finally, CMS states that it is declining to propose a definition for specialty pharmacy at this time because this could prematurely interfere with the rapidly changing pharmacy marketplace.

CVS Health supports CMS's decision to define a mail pharmacy and clarify the definition of a retail pharmacy so as to reduce confusion in the market place. We also agree that an essential element of a mail order pharmacy is the dispensing an extended day supply by common carrier and for a retail pharmacy is to have a walk-in facility for the general public. However, we believe that CMS should clarify aspects of both definitions to ensure that they are understood the same way by all parties and clearly distinguish between retail and mail pharmacies. First, CMS should specify the minimum days' supply to qualify as an extended days' supply and second, since retail pharmacies may dispense extended days' supplies and a Part D plan design may provide for the same cost sharing at mail and retail[10], CMS should clarify that in order to qualify as a mail order pharmacy, a pharmacy also must deliver primarily through mail or common carrier and is subject to specific mail order terms and conditions. Otherwise many retail pharmacies will meet the definition of a mail pharmacy and vice versa, which will only lead to more, rather than less, confusion.

CVS Health views the clarification of a retail pharmacy definition as a positive and necessary update for the following reasons:

1. It will lessen member confusion and potentially provide parameters from a member perspective regarding what the term "retail" entails and what the term "pharmacy" denotes.
2. It will potentially reshape contracting strategies to account for nontraditional pharmacy types that exist in retail pharmacy networks and potentially result in CMS developing one or more other pharmacy types to account for dispensing entities that do not qualify as traditional "licensed retail pharmacy dispensing medications to the local walk-in general public."

Part D members use personalized or on-line pharmacy directories with the understanding that the pharmacies listed in these directories are accessible and amenable to walk-in traffic. Therefore,

offered to a subset of pharmacies); 70 Fed. Reg. at 4283 ("These details are up to the plans and their arrangements with pharmacists and other providers. We do not believe the MMA provides us with the authority to establish fee schedules or interfere with the contracts between plans and providers.") (Discussing medication therapy management fees).

[10] CMS acknowledges this in the preamble at 82 Fed. Reg. 56410, stating "Part D plan sponsors may establish unique non-preferred mail order cost-sharing, or may establish such non-preferred mail-order cost sharing commensurate with those for retail pharmacies."

when a "nontraditional" pharmacy type is allowed to participate in the retail pharmacy network due to AWP requirements, it is displayed as a retail pharmacy in associated directory listings on websites and/or mailed directly to members, and members are led to believe that the pharmacy has a retail store-front location that is easily accessible during documented hours and not closed to any of the local, walk-in general public who may want to get a covered item filled. When such access is not available as is often the case with non-traditional pharmacies, it causes significant inconvenience, frustration and annoyance to members.

Nontraditional or “other” pharmacy types may include but are not limited to dispensing physician offices, clinic pharmacies aligned with disease or condition-specific medical clinics, hospital pharmacies, and mail order pharmacies in retail networks that may have limited or no ability to manage local walk-in patients (usually due to limited inventory). CVS Health recommends that in order to be considered a retail pharmacy for Part D purposes, a pharmacy should have the following (or a preponderance of the following) features:

- Presence of accurate store-front pharmacy signage identifying the retail pharmacy and located on the same premises as the actual door to access the pharmacy
- Easy front door access—open to the public during stated business hours—that does not require badge or special access to gain entry
- Physical address location that indicates it is a standard retail "brick and mortar" storefront (i.e., not in a warehouse district, non-retail zoned area or an area that requires other payment for services in order to access filling a prescription)
- Active, working cash register and associated equipment to complete various financial transactions (e.g., cash, credit/debit) in order to pay for covered, eligible items (over-the-counter and prescription medications)
- Posted standard hours open with access to a pharmacist in charge (PIC) who should be in residence (in accordance with applicable laws)
- Maintains adequate prescription drug inventory on hand to meet the needs of the local walk-in customers
- Complies with all CMS requirements/guidance for local walk-in customers (e.g., posting required notices, collecting appropriate copays)

CVS Health supports CMS’s decision not to provide a definition for specialty pharmacy, and agrees that any confusion between pharmacy types and the permissible dispensing of specialty medications in Part D can be addressed through a better delineation of the distinction between mail and retail pharmacies, and CMS’s clearly articulated guidance on when it is and is not permissible to restrict the dispensing of specialty medications.

Treatment of Accreditation and Other Similar any Willing Pharmacy Requirements in Standards Terms and Conditions.

CMS states that there is a role for pharmacy accreditation, to the extent this is to promote quality assurance, and adds that it particularly supports Part D sponsors negotiating accreditation requirements in exchange for designating a pharmacy as a specialty or preferred pharmacy. However, it does not support Part D sponsor-or PBM-specific credentialing criteria in lieu of, or in addition to, accreditation by recognized accrediting organizations apart from drug-specific

limited dispensing criteria such as FDA mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such requirements cannot be met by network pharmacies and which are waived for certain pharmacies, which calls into question the need for such requirements.

CVS Health appreciates CMS' recognition of the importance of accreditation to promote quality assurance. We also agree that pharmacies should not be required to meet multiple, duplicative accreditation or credentialing requirements. However, we are concerned that CMS's dismissal of plan or PBM-specific credentialing requirements is too sweeping in that the terms "accreditation" and "credentialing" have different meanings and perform different purposes. They can cover a wide range of subjects and activities which are not duplicative or overlapping, and which serve different purposes One example of additional credentialing that CVS Health (Caremark) requires is for pharmacies that want to dispense complex compounded drugs, since this requires higher levels of effort and expertise (such as sterile compounds). The complex compound credentialling process adds an additional level of scrutiny and requirements that helps validate that accurate pharmacy protocols, specific site requirements and appropriate required documentation are in place at the pharmacy regarding patient safety. CMS itself requires that MA organizations have in place a credentialing process for certain providers, one element of which is that the provider have been reviewed and approved by an accrediting agency.[11] Moreover, in deciding to substitute the preclusion list concept for the recently imposed provider enrollment, CMS continues to maintain that, despite potential duplication of effort, "Medicare enrollment, in conjunction with MA credentialing, is the most thorough means of confirming a provider's compliance with Medicare requirements and of verifying the provider's qualifications to furnish services and items."[12]

We are also concerned that in discussing accreditation requirements for quality assurance purposes, CMS suggests that it might be appropriate to require this in return for designation as a specialty or preferred pharmacy. While we understand and agree that it may appropriate in certain circumstances to require additional accreditation for specialty pharmacies, given the more complex medical conditions, additional clinical expertise and medication special handling that may be involved, we see no necessary connection with preferred pharmacy status which, by definition, relates solely to drug costs.

We are especially troubled by CMS's statement that the waiver of a particular standard term or condition for a certain pharmacy or subset of pharmacies means that the term was not reasonable or relevant in the first instance, and proves that the term was not necessary for the ability of a pharmacy to perform its core functions. While we understand and agree with CMS's concern that Part D sponsors not be permitted to arbitrarily impose more burdensome standard terms and conditions on some similarly situated pharmacies and not others, we are concerned that CMS's statement does not simply address these abusive situations, but if read literally, would effectively preclude Part D sponsors from varying their standard terms and conditions at all, even in circumstances that CMS currently allows. CMS's statement assumes that standard terms and conditions should consist of nothing more than the bare essential requirements for a pharmacy to

[11] See 42 CFR 423.204(a) and (b).

[12] See 82 Fed. Reg. at 56448.

function. While this may be the case for a pharmacy to be licensed, it has never been CMS's position for any Medicare provider that mere licensure (or the ability to perform the core functions of that type of provider) is the only requirement for Medicare participation, and the same holds for pharmacy participation in Part D. Similarly, the standard terms and conditions for a particular type of pharmacy extend beyond bare minimum functional standards, and reflect a Part D plan's expectations based on the needs and safety of its Part D enrollees. Thus, it may include requirements related to drug counseling, medication management therapy, and e-prescribing, to name a few. However, Part D plans must – and always have – been willing to consider whether the circumstances of a particular pharmacy or subset of pharmacies warrant waiver or variation of a standard term and condition, such as where it would impose an undue or costly burden on the pharmacy that is not commensurate with the benefit in that pharmacy setting. An example is the waiver of certain accreditation requirements for pharmacies on the Aleutian Islands because those pharmacies are needed for access in such a remote area. Another example is CMS's own waiver of certain pharmacy requirements, such as real time claims processing, for I/T/U pharmacies. These waivers and others that are reasonable and appropriate in the circumstances would no longer be allowed (or otherwise the waived terms would no longer be allowed to be included in a plan's standard terms and conditions) under CMS's proposed re-interpretation of what it considers to be reasonable and relevant terms and conditions. Conversely, just because we have justification to vary a standard in one part of the country, such as the Aleutian Islands example due to access necessity, this does not mean this accommodation should have to be made in other areas where this access condition does not exist, such as a pharmacy located in New York City.

Finally, we are troubled by CMS's apparent objection, based purely on anecdotal reports, to Part D sponsors waiving certain standard terms and conditions "even for certain pharmacies that received preferred pharmacy status." Without knowing the circumstances, including whether the same waiver was offered to other similarly situated pharmacies, it is not possible to say whether the Part D sponsor(s) in question acted in accordance with CMS's policy allowing plans to vary standard terms and conditions to meet access requirements. It is especially troubling that CMS appears to be suggesting that this policy may not apply to a pharmacy simply because it is or may become a preferred pharmacy. This designation may have no bearing on the term waived, and the reasons for waiving a standard term, namely, to encourage network participation, could apply equally to a pharmacy that will have preferred status. For example, if there is only one retail pharmacy in a certain rural area, a Part D plan may waive or vary a standard term and condition so that members in that area have convenient access to at least one network pharmacy. In addition, and consistent with CMS' own focus on ensuring meaningful access to preferred pharmacies[13], the plan may need to designate the pharmacy as preferred in order to avoid its preferred pharmacy network being deemed an "outlier" by CMS. Given the different scenarios possible and the factual nature of these determinations, we are troubled that CMS appears to be pre-judging these situations, and are especially troubled that it is doing so based on anecdotal

[13] See, for example, 2016 CY Call Letter (April 6, 2015), pp. 153 ("*In the CY 2015 Call Letter, CMS announced that we had received complaints from interested parties that some Part D plan sponsors were not providing their enrollees with reasonable access to network pharmacies that offered preferred cost sharing. CMS noted that we were concerned that beneficiaries might be misled into selecting plans based on advertised low preferred cost sharing only to find later that no preferred cost sharing pharmacies (PCSPs) were located within a reasonable distance from their residence*").

reports without providing stakeholders with sufficient information about the situation to be able to meaningfully comment on it.

Timing of Contracting Requirements

CVS Health already adheres to the proposed timelines. However, these timelines fail to adequately address the fact that there may be plan changes (which can occur through the course of the current plan year and prior to the plan year for which standard terms and conditions must be made available), up to and after the September 15th deadline, which would not be reflected in the standard terms and conditions made available by September 15th. The September 15th deadline therefore poses limitations on responding Part D plan changes and last-minute requests that could easily occur during the enrollment period beginning mid-October, especially regarding preferred network composition and vetting last-minute requests from providers and/or plans requesting pharmacy additions in preferred network participation. If this deadline is required, it does not allow for standard exceptions and necessary updates to occur prior to the plan year, and may jeopardize smooth transitions from one plan year to the next by causing exceptions and updates to occur well into the next plan year.

13. Changes to the Days' Supply Required by the Part D Transition Process.

Page(s): 56411-56412

We support the CMS proposal to shorten the required transition days' supply in the Long Term Care (LTC) setting to be the same days' supply as the outpatient setting, yet subject to exceptions for certain therapeutic drug classes when a longer transition period is in the clinical best interests of a LTC resident. While some medications can be promptly changed without compromising the medical condition of a LTC resident, other medications require more gradual transitions to reduce the risk of adverse events and to allow time for prescriber evaluation, since LTC residents are often seriously-ill, medically-fragile, elderly, and sensitive to drug regimen changes. Antidepressants are an example of a therapeutic class that may require a longer transition period for a LTC resident, given it typically takes 30 days or longer to evaluate whether it is effective. Besides antidepressants, at least the following additional therapeutic drug classes merit an exception for clinical reasons from a required month's supply transition fill policy in LTC: anticoagulants; anticonvulsants; antiretrovirals; antineoplastics; beta-blockers for cardiovascular disease; disease-modifying agents in rheumatoid arthritis; Multiple Sclerosis drugs; and Parkinson's disease drugs.

We note that in the LTC setting, dispensing increments are typically a 28-31 day supply for generics and a 14-day-or-less supply for brand drugs, or smaller quantities. In other words, transition fills in LTC are not dispensed in one increment, with the full 91/98 days allowed. LTC facilities do not stock such quantities of prescriptions, in their specialized packaging, on a facility's medication cart.

CVS Health welcomes the opportunity to discuss with CMS in more detail this proposed exception process for transition fills for certain therapeutic drug classes in the LTC setting.

We also support the transition supply change to be a month's supply based on the Plan Sponsor's approved Bid. While we support the technical change of a transition supply being a month's supply, we would like clarification regarding providing a transition supply for an unbreakable package. In the proposed rule, the example of an unbreakable package of 28-day supply is given. Using this example, when a drug is packaged in a four (4) week/28 day supply, we believe that it is the manufacturer's intention that this is a month's supply of the drug. We recommend that CMS confirm that drugs packaged in an unbreakable 28 day supply to meet the one month supply requirement under transition fill.

14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes.

Page(s): 56413-56416

We appreciate additional flexibility to manage formularies and support the CMS proposal that enables Part D plans to immediately substitute newly released equivalent generics for brand name drugs and the CMS proposal regarding Midyear Formulary changes.

In the proposal, CMS will permit Part D Sponsors to substitute a generic drug for a brand name drug immediately rather than make the change effective, for instance, at the start of the next month and requested comment on whether there is reason to require such a delay. We do not believe a delay should be required. As noted in the proposed rule, immediate substitution is a well-established practice in commercial plans, and would be additionally supported by the provision of both an advance general notice that such substitutions may occur and a requirement for retrospective direct notice to affected enrollees. However, we feel it is very important that plans should also retain the flexibility to implement these changes on a later timeframe without additional advance notice requirements. For example, market dynamics including availability and pricing are among the factors plans consider when evaluating a potential formulary change upon the approval of a new generic. Often, especially in the first six months of new generic launch, there may be a single or few suppliers of the generic, and during this time pricing remains similar to the brand. In this case, plans may defer implementing a formulary change until the generic attains an economic advantage compared to the brand. However, we understand the hesitancy to permit substitution of any generics regardless of how long they have been on the market. Therefore we recommend that a practical time period of 12 months should be adopted after the generic has been released to the market. This time period allows time for the product to become more widely available and for the price points to settle.

In the proposal section discussing expedited substitution of certain generics, CMS indicated that online posting of formulary changes is considered sufficient notice for SPAPs, entities providing other coverage, authorized prescribers, network pharmacies, and pharmacists. Please clarify if this guidance applies to all types of midyear negative formulary changes or is otherwise limited.

Please clarify if the proposal to change the notice and refill requirements for certain other midyear formulary changes incorporates all other maintenance changes (i.e., generic substitutions and other types of maintenance changes that do not otherwise meet requirements for immediate implementation) and non-maintenance changes. Also clarify if the Plan Sponsor

can implement these midyear formulary changes any time of year or if the current timing limitations would remain.

If the proposal is not inclusive of non-maintenance changes, we also encourage CMS to consider modifying notice requirements to allow plans additional flexibility to make these types of changes, e.g., in response to changing market conditions. Because these changes do not affect enrollees currently taking the drug, notification requirements of CMS-approved non-maintenance changes could be streamlined to 30 days advance notice to enrollees, SPAPs, entities providing other coverage, authorized prescribers, network pharmacies, and pharmacists via online posting. In addition, CMS should consider allowing plans to update any hard copy formularies via errata sheets that are distributed to members through normal course of business, instead of requiring the mailing of errata sheets to all enrollees no less than monthly.

The proposal indicates that CMS does not believe a transition policy would be appropriate for immediate generic substitutions. Please clarify if CMS believes the transition process would not be appropriate only for expedited substitution of certain newly approved generics or also for other generic substitutions that are implemented on a later timeframe.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS cost-sharing.

Page(s): 56416-56417

We support the proposed rule to treat biosimilar drug products (follow-on biological products) as generics for cost-sharing purposes for non-LIS (non-Low Income Subsidy) beneficiaries in the catastrophic portion of the benefit and for LIS beneficiaries throughout all phases of the benefit. Please note that organizations will need to make complex systems updates in order to accommodate this change because Industry Standards identify follow-on biologic drugs as brands; however, these same follow-on biologic drug entities will need to process as generics for certain benefit processing under this proposed rule.

Currently, biosimilars are non-applicable drugs for purposes of establishing coverage gap cost sharing under the Part D benefit and are not discounted or otherwise subject to Discount Program requirements. In order for biosimilars to be more effective for Medicare Part D, we recommend that CMS also consider waiving the definition of “applicable drug” for Medicare Part D purposes regarding the Coverage Gap Discount program in order to include biosimilars in the discount program.

Additionally, we suggest that CMS work with FDA to develop an industry standard that distinguishes the application difference in the approval pathway of the biologic product versus the biosimilar product, similar to the NDA and ANDA Application Status designations. Drugs approved via the New Drug Application (NDA) process follows either the 505(b)(1) or the 505(b)(2) regulatory pathway. Drugs approved via the Abbreviated New Drug Application (ANDA) process follows the 505(j) regulatory pathway. However for biologics and biosimilars, the application status designation is the same, which is Biologic License Application (BLA). The application pathways are different, so it is feasible that an industry standard could be established

to distinguish the two product types. The referenced biologic product is approved via the 351(a) Biologic License Application regulatory pathway. The follow-on biologic product is approved via the 351(k) Biologic License Application regulatory pathway.

16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences.

Page(s): 56417 - 56419

CVS Health supports CMS's decision to remove the Meaningful Difference for Enhanced Alternative vs. Enhanced Alternative (EA) plans. CVS Health believes the current Out of Pocket Cost (OOPC) model has some limitations and limits innovative plan designs. CVS Health also encourages CMS to review the OOPC tool and look into alternative methods of measuring the meaningful difference between the basic plan and the first enhanced alternative plan.

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale.

Page(s): 56419 – 56428

CMS requests comments on possible policies that would apply a minimum percentage of manufacturer rebates and all pharmacy performance network price adjustments at the point of sale (POS). The agency makes no formal proposals related to POS rebates, but states that feedback received will be used for consideration in future rulemaking.

CVS Health strongly opposes any policy that would mandate the application of any percentage of drug manufacturer rebates or pharmacy price adjustments at POS.

Manufacturer Rebates

Currently, Part D Plan sponsors administer rebates for each National Drug Code (NDC) consistently across all Contracts and Plan Benefit Package IDs. While CVS/Caremark is fully capable of applying drug manufacturer rebates at POS—and, in fact, does so in the commercial space with over 11.6 million lives covered under these plans—for several reasons explained below, we do not support this practice in Part D, and note that the practice has not seen widespread adoption by most Part D plans. Rebate savings in Part D are instead generally reported to CMS through Direct and Indirect Remuneration (DIR) reporting and are used to lower premiums for all members, rather than to lower costs at POS for only the few beneficiaries who require expensive, rebated drugs.

CMS seems to suggest in the preamble that POS rebates are necessary, in part, because any manufacturer rebates that are greater than expected after the plan bid has been submitted are kept by PBMs and Part D plans as extra profit, and not used to lower premiums. This assertion is inaccurate and incomplete. In fact, any extra profits are shared through risk corridor payments,

as is required by statute. The Part D risk corridor program incentivizes Part D plans to accurately project DIR in their bids: 0% of savings or losses within 5% of the target are shared by the plan, 50% of savings or losses within 5-10% of the target are shared by the plan, and 80% of savings or losses more than 10% of the target are shared. This shows how plans are penalized for under projecting DIR in their bids—the greater the underreporting, the greater percentage shared with the government. The policy in the RFI is a solution in search of a problem. There is not a problem of plans retaining rebates as profits, because the problem does not exist.

As CMS' own impact table (Table 10A) shows, requiring manufacturer rebates to be passed through at POS would increase government spending (and thus taxpayer costs), and provide a financial windfall for manufacturers. In addition, such a policy would provide manufacturers with insights into rebates across plans and encourage them to reduce rebates, increasing drug price volatility and leading to higher drug costs, overall. Finally, and perhaps most importantly for the program, such a policy would increase beneficiary premiums, which could result in fewer people signing up for Part D and thus reduce Medicare beneficiary access to medications.

Established in 2006 to provide America's seniors with prescription drug coverage, the Medicare Part D program features rigorous competition among Part D plans and robust negotiations between PBMs, drug manufacturers, and pharmacies to provide both beneficiaries and the government with the highest quality care at the lowest possible cost. Program costs have been far below the original CBO projections and consumer satisfaction is high—consistently near 90%. Average monthly premiums have also been stable and low, with the average 2018 monthly premium at $33.50. The program has proven successful and major programmatic changes must be considered carefully.

CVS Health is working hard to address rising prescription drug costs, and understands the federal government's interest in doing the same. The government, however, should not be pursuing misguided policies that, instead of productively addressing drug costs, would result in higher premiums to 42 million seniors and disabled Medicare beneficiaries while benefitting drug manufacturers and substantially increasing federal government costs.

- **The Policy Would Increase Government Spending/Taxpayer Costs**

CMS itself forecasts in the financial impact tables included in the preamble to the proposed rule that requiring Part D Plans to estimate and apply manufacturer rebates at the POS would increase beneficiary premiums by up to $28 billion and taxpayer costs by up to $82 billion over the next decade. (82 *Fed. Reg.* 56,425).

- **The Policy Would Provide a Financial Windfall for Drug Manufacturers and Increase Drug Costs**

The financial impact tables also show that a policy of applying rebates at POS would not only increase costs to taxpayers, but simultaneously create a financial windfall for manufacturers, who would be excused from providing up to $29 billion in coverage gap discounts for which they would otherwise be responsible.

CVS Health is concerned that this policy would also provide manufacturers with insight into what rebates are provided on what drugs to what PBMs and thus give drug manufacturers the information and the incentives to lower the rebates it provides to Medicare Part D plans. Specifically, manufacturers would be able to see what rebate levels are associated with competing products from other manufacturers, allowing them to know where they do not have to provide as deep a rebate for formulary inclusion or tier placement. Making this proprietary information available through a POS rebate policy would reduce manufacturer competition and PBM negotiation leverage, resulting in higher program costs overall.

We are also concerned that this proposal may increase overall drug costs by encouraging beneficiaries to utilize brand name drugs rather than lower-cost generic drugs due to the lower member cost sharing at POS for the brand name drugs.

- **The Policy Would Increase Premiums for All Beneficiaries**

Currently, as the CMS' data shows from the financial impact tables, rebate savings are used by Part D plans to lower premiums across the board for all members. A POS rebates policy would result in premiums increasing for all beneficiaries as rebates could not be used to lower premiums, and costs would be lower at POS for only the few beneficiaries who require expensive drugs that offer rebates. To provide context, over 85% of the drugs utilized under the Part D program are generics, which have no rebates. Additionally, most brand name drugs in the six protected classes do not provide rebates (as manufacturers of these drugs have no incentive to offer rebates), and many high-cost brand name drugs also do not provide rebates. Approximately 45% of members utilize only generic medications (which are not rebated) or do not use prescription drugs at all, and will thus see no benefit from a POS rebate policy. Instead, they will experience only higher premiums. Another 25% of members use mostly generic medications and some brand name drugs, but will not see a sufficient reduction in out of pocket costs to offset the premium increases. Based on an internal CVS Health analysis of the beneficiaries served by SilverScript, only 15% would clearly benefit from a POS rebate policy (although at the cost of higher premiums) with another 15% in a position that they may or may not benefit from such a requirement. The remaining 70% would see increased costs with no commensurate increase in service, access, or other benefit.

CMS's financial impact tables themselves show an increase in beneficiary premiums across all possible policy scenarios. Table 10C shows premium increases of up to 11% over 10 years. The tables, however, assume total manufacturer rebates of 20% (footnote 53, 82 *Fed. Reg.* 56,425), which is too low. Rebates across the industry are more likely to be higher than that, and thus the numbers reported in the impact tables are lower than what they should be. Implementation of this policy is likely to result in costs and premium increases higher than what CMS has indicated.

An additional negative impact is that higher premiums will encourage members who have low/no utilization of drugs to not enroll in a Medicare Part D plan, thereby reducing the overall number of members in the program. Those remaining in the program would be confused by the sudden spike in premiums for no clear benefit, which would increase member complaints and consumer dissatisfaction.

- **The Policy Would Introduce Additional Administrative Concerns**

CVS Health also notes that a number of important practice, policy, and operational issues are not addressed in the RFI, such as adjudication in the coverage gap, the application of POS rebates to EGWPs, the handling of non-rebate eligible claims such as 340B claims, claims from out of network pharmacies, and paper claims.

Additionally, such a policy would significantly increase administrative costs for both Part D plans and CMS that have not been acknowledged. For example, many CMS systems would need extensive revisions, such as the Part D risk score model, Plan Finder, PDE reporting, and DIR reporting.

Illustration

To illustrate some of our key concerns with the POS rebates policy in the RFI, particularly with the blended rebate approach, we have developed a POS rebate example, below. The assumed plan is a typical Part D plan that is common in today's market, with a $0.00 deductible; co-pays on Tiers 1, 2, and 3; and co-insurance on Tiers 4 and 5.

We have assumed three rebated brand drugs (A, B, C) as illustrated in the table below:

POS Illustration								
Drug	Number of Prescriptions	Drug Ingredient cost	Rebate	Final Negotiated Price	Drug Tier Placement	Tier co-pay/ co-insurance	Net Cost after Negotiated Price and Co-pay	Member cost
A	500	$500.00	65%	$175.00	3	$40.00	$135.00	$40.00
B	400	$450.00	60%	$180.00	3	$40.00	$140.00	$40.00
C	100	$300.00	10%	$270.00	4	42%	$144.00	$126.00

The illustration shows the following:

- Following the point of sale rebate example methodology put forth in the proposed rule, we have 59.46% calculated as [(500 X $500 X 65% +400 X $450 X 60% + 100 X $300 X 10%) divided by (500X $500 + 400 X $450 +100 X $300)]. We then applied the 50% rebate at POS, as used in the CMS example, to get a 29.7% POS rebate for each of the three drugs.
- The rebate applied for drug C is higher than the actual rebate received, creating a confusing, opaque rebate application that reduces, rather than improves, transparency.
- The POS rebate does not impact out of pocket costs for members who use drugs A or B. The member would still pay $40.00 for the prescription. Only members taking the high negotiated priced drug benefit with their co-insurance falling from $126.00 to $88.58.

- If we assume that Drug A goes generic, the weighted rebate falls to 52.86% and the applied rebate would be 26.4%.
- A member taking drug B would not see a change in out of pocket costs under a POS rebate policy. They would still pay $40.00 while the members taking drug C would see an increase from $88.58 to $92.74. This could cause member confusion and complaints.

The illustration highlights several significant issues with the blended rebate approach:

- It would unfairly require higher rebates than are actually received for some drugs.
- It would not benefit members taking rebated brands on co-payment tiers.
- When a brand goes generic, members taking other drugs would see their out of pocket costs increase.
- If the CMS cost models are based on co-insurance, the reduction in member out of pocket costs is overstated in the CMS analyses.
- Manufacturers offering lower rebates benefit from the higher rebates provided by other manufacturers in the category. This will ultimately result in rebates decreasing to a lower common level, since manufacturers will not want to subsidize competitor products. In the example, it is unlikely that manufacturers A and B would maintain the current rebate when manufacture C benefits from their rebates at point of sale.

Several other issues need further elaboration:

- The blended rebate policy option operates at the plan level. This means that, for a sponsor offering two plans in each region, each rebate contract would now be administered at both POS and for DIR reporting as 68 different contracts (34 regions multiplied by 2 plans per region) rather than 1 contract. Administratively, this adds complexity and cost, requiring frequent re-calculation of the blended rebate rate. Sufficient (and significant) lead time would be needed to accommodate the programming changes required for claims adjudication, rebate systems, DIR reporting, and all downstream systems and reports.
- Risk scores would need to be revised based on the revised net cost structure. Attention to LIS members would be particularly critical so as to not discourage plans from seeking LIS members.
- Revisions to Plan Finder would be vexing. Every plan would face a more complex pricing upload to CMS. Due to the blended rebates and periodic changes with the blending, Plan Finder would be a less reliable tool for members. Unless Plan Finder reflects pharmacy level variations, pricing at some pharmacies, such as 340B pharmacies, the tool will be highly inaccurate for members.
- We do not see how blended rebates increase net cost transparency. Rebates vary greatly from drug to drug and manufacturer to manufacturer. Blending creates the false impression that rebates by class are consistent.

If CMS is serious about exploring policies mandating some level of POS rebates, it must work directly with plans to assess impacts—specifically, we recommend the agency collect pseudo bids from plans to get an accurate sense of the financial impact such a policy would have on plans and premiums before CMS considers any future rulemaking on this topic.

Pharmacy Price Concessions

CMS is also requesting information on a possible policy that would impact pharmacy performance payment arrangements and DIR—specifically, asking stakeholders to comment on whether it should mandate that all pharmacy price concessions be reflected in a drug's negotiated price at POS. This mandate would apply even to price concessions that are contingent upon pharmacy performance. CVS Health strongly opposes any policy that would adversely impact our Part D plan clients and the beneficiaries we serve, and this POS policy would do both.

- **Applying All Pharmacy Price Concessions to Drug Prices at POS Would Severely Impede Pay-for-Performance Pharmacy Programs**

Congress and CMS have taken steps toward a more value-based health care payment system through the adoption of pay-for-performance methodologies in traditional Medicare and the Medicare Advantage program. Similar to how the Medicare fee-for-service system incentivizes other providers such as physicians and hospitals, incentivizing pharmacies to improve performance and lower costs increases value for Medicare beneficiaries. Under performance-based pharmacy arrangements negotiated by Part D plans, pharmacies can receive positive or negative payment adjustments based upon criteria such as:

- Formulary compliance;
- Helping beneficiaries remain adherent to their prescribed regimens, such as statin and diabetes drugs;
- Reducing inappropriate drug use and/or overutilization;
- Increasing beneficiary participation in Medicare medication therapy management consultations and comprehensive medication reviews;
- Engaging beneficiaries to participate in, and reporting metrics related to, diabetes disease management programs; and
- Actively engaging in customer satisfaction and service programs.

These performance criteria are generally based upon areas CMS has identified as indicating quality services in Part D, and most of these are used by CMS through its STAR Ratings system to evaluate Medicare Advantage and Part D plans.

By definition, these metrics require an evaluation of pharmacy activity over time and cannot be accurately calculated or meaningfully reflected in the claim adjudicated at POS or on a per-claim basis.

CVS Caremark aims to make its pharmacy performance network program as transparent as possible so that pharmacies know exactly what they will be measured on and how the payments are calculated. This is important not only as a matter of fairness to pharmacies, but also because it makes the performance payment system more effective in that pharmacies know what activities are valued and rewarded from a quality and beneficiary services perspective. We do this by communicating with pharmacies in a number of ways, including providing all pricing components in our contracts with pharmacies; providing exhaustive performance notifications;

engaging in face-to-face interactions with pharmacies at chain and independent pharmacy trade shows; providing on-demand teleconference calls for independent pharmacies, chain pharmacies, and pharmacy service administration organizations (PSAOs); and making available electronic comprehensive pharmacy reports to pharmacies 24 hours a day, 7 days a week on our secure pharmacy portal. In addition, CVS Caremark provides retail pharmacies with a number of performance-related resources through our partner vendors (*e.g.*, medication therapy management (MTM) vendors, vendors working on STARS ratings across the industry, etc.), and provides all claims and payment details, including the collection and payment of performance payments to pharmacies in accordance with the NCPDP electronic claims adjudication and payment standards for the retail pharmacy industry.

Policies that attempt to move pharmacy payments currently accounted for under DIR to POS or per-claim reimbursements would severely constrain our ability to implement these types of valuable pay-for-performance programs for pharmacies. Furthermore, limiting plans' ability to utilize performance-based payment models for pharmacies runs counter to the overwhelming trend in the health care system toward reimbursement reform that takes into account performance and value in order to improve the quality of care and reduce health costs.

- **Applying All Pharmacy Price Concessions to Drug Prices at POS Would Limit the Ability of Retail Pharmacies to Provide Value**

By limiting the ability of Part D plans to use pay-for-performance models for pharmacies, this policy would abruptly shift pharmacy reimbursement in Part D from a value-based payment model to an activity-based payment model. This would be a major step backwards for retail pharmacies, since it would greatly diminish their critical role in reducing medical costs associated with medication non-adherence and gaps in pharmacotherapy/care for Part D beneficiaries.

It would also disrupt and reverse the momentum towards greater pharmacy and medical collaboration to provide a well-coordinated continuum of care for Part D enrollees in that pharmacies would no longer share the same performance-based incentives as their medical professional counterparts. By drastically limiting the way in which pharmacy payments can be made, the policy effectively eliminates pay-for-performance and value-based payment models as a meaningful payment model for pharmacies. This will, in turn, have repercussions throughout the health care system, reducing the overall effectiveness of these models in bringing down health care costs.

- **Applying All Pharmacy Price Concessions to Drug Prices at POS Would Increase Costs to Part D Plans, Beneficiaries, and Taxpayers**

Under the approach put forth by CMS, the negotiated price made available at POS would represent the lowest possible reimbursement that a network pharmacy could receive from a particular Part D plan sponsor for a covered Part D drug. The negotiated price would include all price concessions that could potentially flow from network pharmacies, as well as dispensing fees, but exclude any additional contingent amount that could flow to network pharmacies. DIR

reporting would include any additional contingent payments to network pharmacies post-POS as negative DIR.

Currently, Part D plans are required to include all pharmacy price concessions and incentive payments to pharmacies which can be reasonably determined at POS. Pharmacy payment adjustments that cannot be reasonably be determined at POS, such as incentive payments or penalties that are based on pharmacy performance over a period of time, can be made after POS and reflected in the DIR report. To the extent these result in a net positive payment to the Part D plan, these amounts can be used by Part D plans to reduce premiums for all plan members. Over the 2017-2026 period, DIR negotiated by Part D plans and their PBMs is projected to save $259.6 billion for the federal government and $48.7 billion in beneficiary premiums (Milliman study, July 2017).

- **Applying All Pharmacy Price Concessions to Drug Prices at POS Would Cause Unintended, Adverse Pricing Reductions**

The policy in the RFI would require that pharmacies be paid the lowest possible amount at POS, and then to the extent that a pharmacy actual payment should be higher, this would be paid after POS in the form of negative DIR. This policy would eliminate the cash float that is currently provided to all pharmacies in performance networks—*i.e.*, pharmacies will no longer have the benefit of the cash associated with a higher possible payment during the performance measurement period. Lowest cost pricing also eliminates the ability of pharmacies to distinguish themselves and be reimbursed for quality interventions, a disadvantage for high-performing pharmacies and for beneficiaries.

- **Applying All Pharmacy Price Concessions to Drug Prices at POS Would Cause all Part D Plans to Stop Pay-for-Performance Pharmacy Programs**

As financial impact Table 11 shows, the imposition of applying all pharmacy price concessions at the POS would increase both beneficiary premiums and government costs and also provide pharmaceutical manufacturers with a financial windfall in reduced spending. However, any Part D plan can avoid larger increases in premiums by simply foregoing a pay-for-performance program that would be counted as positive DIR, as outlined by the policy contained in the RFI. Since positive DIR would increase premiums, beyond moving price concessions to the POS, Part D plans without pay-for-performance programs in place would have lower premiums and be more competitive versus plans with such programs. The policy outlined in the RFI would incentivize all plans to drop their pay-for-performance programs.

Congressional Action More Appropriate

Both of the policies outlined in the RFI involve substantial changes to the Part D benefit. If these changes, or similar ones, were to be implemented, billions of dollars in costs and savings would be shifted between beneficiaries, the government, and pharmaceutical manufacturers. Changes of this significant size are best left to Congress for legislative action, rather than to federal agencies for regulatory action, because agencies may be constrained by current law in their ability to freely and properly craft a policy that minimizes any negative impact.

For instance, under both the drug manufacturer rebate and pharmacy price concessions policies, pharmaceutical manufacturers receive a windfall. This is due to the 50% discount they must provide to beneficiaries who are in the coverage gap, as the discount would be based on a lower drug price *after* the manufacturer rebates and pharmacy price concessions are applied at the POS. However, if CMS were to reverse this application so that the 50% manufacturer discount is applied *before* the inclusion of manufacturer rebates and pharmacy price concessions, this would create its own set of problems. For instance, in this scenario, because there would be number of brand name drugs with high rebate levels, the cost of the drug in the coverage gap could become close to zero or even negative. This would incentivize manufacturers to offer lower rebate levels than they offer now which would raise the overall cost of the program. Because CMS is constrained by the Affordable Care Act in how the 50% discount is applied, it is constrained in how it minimizes the pharmaceutical manufacturers' windfall. Congress, on the other hand, could look for other ways to reduce or eliminate this windfall that are currently outside of CMS' regulatory authority. If CMS were to conclude that it should move forward with one or both of these policies, we believe it would be more appropriate for CMS to include a legislative proposal on these topics in the President's budget than to try to implement them through rulemaking.

B. Improving the CMS Customer Experience

2. Reducing the Burden of the Compliance Program Training Requirements.

Page(s): 56429-56431 and 56481

CVS Health disagrees with the deletion of the general compliance and fraud, waste, and abuse ("GCFWA") training requirements for First Tier, Downstream, and Related Entities ("FDRs"). Chapter 9 of the Prescription Drug Benefit Manual outlines 7 essential elements of an effective compliance program, which includes a requirement for Effective Training and Education. These elements flow down to FDRs. The proposed change would ostensibly remove Effective Training and Education as an essential element for FDRs. While this may reduce the burden on FDRs, it would increase the burden on plan sponsors, and make FDR accountability more challenging.

Ensuring that FDRs are aware of and train FDR employees on GCFWA allows sponsors to educate FDRs on requirements and hold FDRs accountable to be in compliance with these requirements. Removing training requirements, or requiring "training or retraining as appropriate, when non-compliance or misconduct is identified" (FR 56430), encourages reactive rather than proactive education—this increases the risk of FDR noncompliance with program requirements because FDRs would no longer be required to teach staff how to avoid non-compliance until after an act of non-compliance has occurred. This change has the potential of putting beneficiaries at substantial risk—for example, call centers and pharmacies are high risk FDRs with substantial beneficiary contact. This change in training requirements will impact all FDRs, including these types of high risk entities. CVS Health considers the benefit of protecting the beneficiary through FDR education to outweigh the burden on the FDR to take training.

Holding sponsors accountable for FDR conduct without requiring FDRs to take GCFWA training places a considerable burden on sponsors. Though CMS suggests that sponsors may maintain training requirements using other methods, a CMS requirement related to training and education provides sponsors with substantial support in ensuring FDR accountability. In many ways, sponsors depend on the support of CMS guidance when holding FDRs to requirements. Removing the training requirement completely may impact the ability of sponsors to require effective training and education from their FDRs, as many will not agree to comply with sponsor requirements that are not CMS requirements.

CVS Health suggests that it is possible to provide both flexibility to sponsors and FDRs in training, and to reduce the training burden, without removing the training requirement entirely. CVS Health proposes the following:

- Continue to require GCFWA training, but remove the requirement that the Medicare Learning Network (MLN) content must be utilized. Guidance could specify components to be included in training (such as obligation to report and how to recognize noncompliance and FWA, etc.) and the 'effectiveness' of this training could be reviewed by sponsors during auditing and monitoring. This provides flexibility in approach while still providing sponsors with CMS support in enforcing an important compliance requirement, or
- Continue to use the MLN, but develop a tracking and reporting mechanism such that sponsors and FDRs can use the MLN to verify training completion.

CVS Health opposes the elimination of the general compliance and fraud, waste, and abuse ("GCFWA") training requirements for FDRs.

4. Revisions to Timing and Method of Disclosure Requirements.

Page(s): 56339-56340, 56431-56433, 56469

Overall, CVS Health supports the CMS proposed option to provide the Evidence of Coverage (EOC) and Summary of Benefits (SB) electronic delivery (e-delivery) to beneficiaries.

However, CVS Health requests clarity in guidance related to members opting in to receive materials in different media types. As CMS is finalizing the proposed rule please clearly define the beneficiary e-delivery opt-in requirements. We request that plans no longer be required to receive beneficiary opt-in for e-delivery for every communication type. Additionally, we recommend that the Final Rule include a detailed list of documents that will be exempt from the opt-in process.

While CVS Health agrees the beneficiary experience will improve with the option to provide an electronic EOC, we request that CMS allow plans the additional flexibility to include certain information from the EOC into the Annual Notice of Changes (ANOC) to ensure the beneficiary has all the critical information needed in order to make an informed decision. For example, currently, the ANOC only shows the Initial Coverage Stage. We suggest to allow plans the

option to show Annual Deductible, Initial Coverage, Coverage Gap, and Catastrophic Coverage Stages in the ANOC as appropriate per plan type and plan design.

Currently, beneficiaries receive the ANOC packets prior to October 1. We request that the current requirement stay in place and continue to allow the posting of documents online for the future plan year by September 30. Allowing this requirement to continue as is ensures the availability of new plan year information to beneficiaries and Customer Care Centers who are answering beneficiary annual enrollment questions.

5. Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities.

Page(s): 56433-56434, 56437, 56470-56472, 56485-56486

We are in favor of the proposed changes to the definitions related to activities and materials for Communication and Marketing. These changes will provide a clear delineation of those materials that influence an enrollee or member to join or remain in the plan, from those materials that communicate to current members.

We are also in favor of the proposed changes related to materials that will no longer require CMS review. Using the same timeframe and date range as the CMS sample, we filed 313 materials in HPMS, where 101 required CMS prospective review and approval. Based on the proposed changes, we estimate a 16% reduction in HPMS filings.

In Section 8, Table 16 there is reference to 80,110 marketing materials submitted for File and Use or 45-Day review in the 12-month sampling period. There are materials currently submitted today that are not clearly called out as part of what will no longer require HPMS filing for CMS review. Some include CMS Models, Chapter Guidance Exhibits, along with HPMS memo instructions for filing requirements.

We recommend that Standardized Models and Chapter Guidance Exhibits not require HPMS filing for CMS review. Also, that the HPMS Marketing Module Codes and instructions align and are made consistent with the new definitions of marketing and non-marketing materials.

The proposed changes make no mention of non-model materials and CMS review requirements. We request clarification of non-model materials and how the 90/10 non-model rule will be impacted.

Further clarification is requested on Section 8, Table 16: Marketing Material Submission Burden Analysis. There are Marketing Codes and Descriptions that are not clearly described related to the following HPMS codes:

1. 1000-Enrollment Form and Related Docs

   As indicated in Table 16, the only material that will require CMS review within this category is the Enrollment Form (1070). The Member Handbook (1075) and Summary of

Benefits (1099) are currently filed as stand-alone materials, along with the Enrollment Form. These materials are also combined and sent as a kit to a potential enrollee. The Member Handbook and Summary of Benefits include plan benefit and cost-sharing information. We request clarification if these two materials will also be considered "marketing", per the proposed definition. We also recommend updating Table 16 to reflect the inclusion of these materials as those that will fall under the purview of CMS review, should it be the case.

The Pharmacy Directory (1080) currently is identified with a "F" Non-Marketing indicator, yet the Code Usage Instructions state that it must be filed. We request clarification if the Code Usage Instructions will be modified to exclude from CMS review.

2. 1100-ANOC/EOC/LIS Rider

The Combined ANOC/EOC (1127) currently includes filing instructions to include the EOC with the ANOC(s) in a zip file. We recommend that the filing instructions be updated to exclude the EOC from being included in the ANOC zip file. We also propose that the HPMS Category, Code Description and Code Usage Instructions remove reference of the EOC.

3. 2000-Enrollment/Disenrollment/Payment Notices

As indicated in Table 16, the HPMS Code Description only notes "Disenrollment Forms". We recommend that this is updated to "Enrollment/Disenrollment/Payment Notices" to reflect all of the materials within this category.

4. 3000-Claims/Org. Determinations/Appeals/Grievances

As indicated in Table 16, the HPMS Code Description only notes "Grievance Forms". We recommend that this is updated to "Claims/Org. Determinations/Appeals/Grievances" to reflect all of the materials within this category.

5. 4000-Advertising

Envelopes (4034) are currently filed with brackets to indicate the required Medicare Marketing Guidelines (MMG), Appendix 5 mailing statement. We recommend that this category no longer require CMS review.

The Multi-Language Insert (4036) is no longer a CMS model and has since been replaced by Section 1557 requirements. We recommend that this HPMS Code be deactivated.

6. 6000-Presentations/Scripts/Surveys

As indicated in Table 16, the only material that will require CMS review within this category is the Enrollment Script (6015). We request clarification for the disposition of the Sales Script (6013).

8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards.

Page(s): 56339, 56438 – 56440

CVS Pharmacy and CVS Caremark are requesting that a transition period be added as this has worked well for the industry in the past. We suggest voluntary use be the effective date of the Final Rule and the sunset date for version 10.6 be 24 months later.

A transition period would mitigate the risk of healthcare delivery delays and disruption. Additionally, a transition period will allow early adopters to identify any possible problems with documentation or the Standard itself.. As a note, the transition from version 8.1 to 10.6 took approximately three years.

The implementation timeline for the Standard should allow sufficient time for all involved entities to have time for design, development, testing by vendors with vendors, end user testing, software certification, EPCS auditing and training.

CVS Pharmacy and CVS Caremark also recommend that the regulatory compliance date for the NCPDP SCRIPT Standard v2017071 not fall on the first of January due to a possible risk of healthcare delivery delays and disruption.

10. Part D Prescriber Preclusion List (PDP, MA, and PACE).

Page(s): 56441-56454

CVS Health welcomes the CMS proposed change to eliminate the prescriber enrollment requirement and focus on a smaller subset of problematic prescribers. We agree that this change would impact far fewer beneficiaries than the original prescriber enrollment guidance, as the universe of precluded prescribers would be substantially less than the entire universe of prescribers that still needed to enroll in the Medicare program. Notwithstanding the rescission of the prescriber enrollment requirement, the complexity of this overall regulation would make it challenging to implement the requirements with an effective date of January 1, 2019. In particular, we would need at least 12-18 months to program and test our systems once we have received all of the necessary technical guidance on precluded prescribers. As such, we respectfully request that CMS revise the implementation date to no earlier than January 1, 2020.

Prescriber NPI Validation on Part D Claims (pages 56442-56443)

We request clarification from CMS on the rewrite of paragraph 423.120 (c) (5) and associated MACRA requirements. Specifically, in those instances when a pharmacy encounters an issue

with a prescriber NPI and the pharmacy either cannot or does not correct the NPI, are plans still required to outreach to network pharmacies within 24 hours in an attempt to obtain a valid NPI?

Targeted Approach to Part D Prescribers (pages 56443-56445)

We support the CMS decision to remove the enrollment requirements for all prescribers and only focus on problematic prescribers. In the spirit of beneficiary protection, we recommend that CMS develop prescriber preclusion criteria that focuses on beneficiary safety and mitigates the risks of opioid prescribing. Preclusion criteria such as these would curtail potentially harmful prescribing activity from continuing to occur. As such, we also recommend the elimination of the provisional supply requirement as the greatest priority is beneficiary protection.

If CMS adopts our criteria recommendations for precluded prescribers inclusive of eliminating the provisional supply requirement, we also recommend that CMS consider including the precluded prescriber list into the current OIG exclusion list. Combining these lists would streamline implementation of the precluded prescriber requirement by allowing us to leverage the current exclusion prescriber process.

If the above recommendation of combining the precluded prescriber list with the exclusion prescriber list is not possible, we ask CMS to clarify if the precluded prescriber criteria will differ from the current exclusion prescriber criteria to ensure that prescribers are not included on both lists. For example, if a prescriber is listed as both precluded and excluded, we would need to understand which program takes precedence. We would not want to send two different notices to the beneficiary as that would likely cause beneficiary confusion. We therefore recommend that the preclusion and exclusion lists remain separate and distinct from one another with no overlap. However, if this recommendation cannot be realized, we suggest that the exclusion list take precedence over the precluded list.

Replacement of Enrollment Requirement with Preclusion List Requirement (page 56444)

CVS Health requests technical guidance for any PDE changes needed to support the precluded prescriber list process. Specifically, we ask CMS to confirm that plans will no longer need to identify an exception for "other authorized prescribers" on the PDE, and that this field should be submitted with spaces or blanks. In addition, please confirm if CMS anticipates any other changes to the PDE file layout and/or processes related to the proposed precluded prescriber process.

Updates to Preclusion List (pages 56444-56445)

We recommend that CMS provides outreach to the prescriber and the beneficiary prior to including the prescriber on the preclusion list. This would include managing the prescriber notification as outlined in the appeal process from section 4 (page 56446). Specifically, once the appeal period ends and CMS moves forward with adding the prescriber to the preclusion list, CMS would then notify the beneficiary. The prescriber would be added to the precluded list 90 days after the beneficiary notification date. This suggestion would help eliminate the complexities of implementing the provisional supply process, as the 90 days would be built into

the effective date a particular prescriber is added to the preclusion list. CMS could add the end date based on reenrollment bar criteria. In addition, our recommendation of eliminating the provisional supply requirement would streamline point-of-sale edits and avoid potential overlaps or conflicts with other programs, such as transition fill. This addresses the immediate need to address opioid prescribing risks as well as reduces the likelihood of beneficiary disruption at point-of-sale.

We seek clarity on how the precluded prescriber list will function for dual eligible beneficiaries. For Medicare-Medicaid Plans (MMP) and Special Needs Plans (SNP), we recommend that if the prescriber is listed on the preclusion list, then the beneficiary would not be eligible for coverage under both plans. This would eliminate confusion to beneficiaries that have multiple prescriptions that could apply to either the Medicare benefit or the Medicaid benefit.

We ask CMS to clarify when the file layout and location of the preclusion list of prescribers will be available and if CMS intends to make this file publically available for real-time research of the preclusion file.

Provisional Coverage (pages 56445-56446)

We appreciate CMS efforts to simplify the provisional supply requirement. However, it remains highly complex. We therefore strongly recommend that CMS eliminate the point of service provisional supply program in its entirety. If the preclusion list aims to identify problematic prescribers, who through their prescribing activity pose a risk to beneficiaries, then CMS can manage patient access to care based on the post-dated preclusion effective date that is applied to the file. This approach could address CMS' objectives to prevent problematic prescribers from continuing to prescribe opioids. As noted above, supporting a 90 day or any other discretionary period determined by CMS process before adding a prescriber to the preclusion list post-beneficiary notification would eliminate the need to provide provisional coverage at point of service. This would also solve the complexities that plans face in programming systems to track provisional supply and ensuring the program works in conjunction with other Medicare requirements, such as the transition fill program.

If CMS is unable to eliminate the provisional supply requirement in its entirety as we are strongly encouraging, then we have several comments and questions:

Previous technical guidance provided details around provisional supply being a lifetime edit. Specifically, for medications prescribed by a precluded prescriber, this guidance clarified that beneficiaries who change pharmacies during a provisional supply period would still only receive one provisional supply of medication. Similarly, for beneficiaries who change plans within the same contract, if the plan sponsor or its PBM can determine via claims history that the beneficiary has already received a provisional supply, then the provisional supply requirement has been satisfied. Can CMS please confirm that these details from previous technical guidance still apply for provisional coverage?

If a single claim involves both a provisional supply and transition supply, we ask CMS to specify if there will be a combination letter for the beneficiary notice. Our recommendation would be to

keep the notification process separate for the two programs. The provisional supply notice would be less frequent than a transition letter as only the initial dispensing event would trigger a letter advising the beneficiary of the issue with the prescriber. The transition notification should remain status quo and address the medication in question and educate the beneficiary about his/her appeal rights.

The proposed rule states that reasonable efforts must be made by the plan to the prescriber notifying them of a beneficiary who was sent a notice due to the prescriber being precluded. We ask CMS to clarify if this outreach is necessary given that CMS would have previously outreached to the prescriber prior to placement on the precluded list.

CMS notes that they intend to allow the normal Part D rules to apply for safety edits, prior authorization, quantity limits, etc., during the provisional coverage period. All appropriate edits for opioids should also apply during the provisional coverage period as these are designed to prevent serious adverse events. As such, we recommend that all safety and utilization management edits remain the same during the provisional fill period, regardless of medication type (i.e., opioids vs non-opioids).

Appeals (page 56446)

Within the appeals section, the proposal states a letter which includes the prescriber's appeals rights will be sent. We ask CMS to confirm that, prior to adding a prescriber to the preclusion list, the appeal timeframe must be exhausted. If CMS adds the prescriber to the preclusion list while the appeal time frame is still in effect, this could cause beneficiary disruption due to inappropriate rejects, especially if the prescriber's appeal is approved.

It is also noted that CMS will notify prescribers when they are placed on the preclusion list and that notification will include the prescribers' appeal rights to CMS. CMS proposes that a beneficiary could appeal alleged error in applying their prescriber to the preclusion list. Plans will not have any authority over the preclusion list, therefore they will not be able to address or resolve the beneficiary's appeal. There will need to be a process in place to address beneficiary appeals, concerns, and questions about why their prescriber(s) are being added to the preclusion list. Plan sponsors will not have access to the reason for the preclusion to answer such questions.

In Chapter 18, section 40.3.1 of the Prescription Drug Benefit Manual and in previous technical guidance, plans do not have to provide members with the standardized pharmacy notice - CMS-10147 Medicare Prescription Drug Coverage and Your Rights - if the reason for the reject is due to a sanctioned provider who has been excluded from participation in the Medicare program. Please confirm that this exclusion will also apply to claims rejected due to a precluded prescriber.

Summary:
In summary, CVS Health welcomes the CMS proposed change to eliminate the prescriber enrollment requirement and focus on a smaller subset of problematic prescribers. However, given the complexity of this regulation, we do not believe the January 1, 2019 effective date is obtainable with the amount of changes proposed and the amount of comments/questions that

need to be addressed. We are still in need of necessary technical guidance in order to make system changes that include but are not limited to: the file layout of precluded prescribers, PDE changes and updates, and the model notification letter. NCPDP will also be required to make changes as applicable to reject codes, submission clarification codes and/or approved message codes to coincide with precluded prescriber requirements verses the original prescriber enrollment requirements. We recommend making the effective date of this regulation no earlier than January 1, 2020. With a January 1, 2020 effective date, we believe that sufficient advance prescriber and beneficiary notice can occur for those precluded prescribers and will ensure that impacted beneficiaries will no longer have a need to receive provisional supplies. This extended implementation timeframe will also allow CMS time to disseminate all of the outstanding technical guidance required for precluded prescribers, provide time for industry collaboration through NCPDP to ensure appropriate and consistent claims processing standards are developed, and allow time for plans to program their systems successfully with a minimal amount of disruption or access to care.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements.

Page(s): 56456 – 56460, 56472 – 56473, 56488, 56526

Treatment of Fraud Reduction Activities.

CVS Health agrees with the proposed change of designating fraud reduction activities as a quality improvement expense. The regulation is positive and provides an incentive for plans to invest in fraud reduction activities.

Proposed Regulatory Changes to Medicare MLR Reporting Requirements.

CVS Health appreciates the proposed changes to the MLR reporting requirements. The proposed regulation reduces the amount of data provided during the reporting process. However, this change does not reduce the amount of information necessary to create the reporting.

Specifically, we feel there may be an increased audit burden by the plan to support/explain the reported annual Medical Loss Ratio.