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SUBMITTED ELECTRONICALLY

March 5, 2018

Mr. Demetrios Kouzoukas, Esq.
CMS Principal Deputy Administrator and Director,
Center for Medicare
U.S. Department of Health and Human Services, Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-2017-0163; Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter

Dear Deputy Administrator Kouzoukas:

Express Scripts appreciates the opportunity to submit our comments on CMS-2017-0163, the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter (Draft Call Letter). Express Scripts (ESI) is a pharmacy benefit manager (PBM) that provides integrated PBM services including network-pharmacy claims processing, home delivery services, specialty benefit management, benefit-design consultation, drug-utilization review, formulary management, and medical and drug-data analysis services for more than 80 million Americans—5 million of whom are Medicare beneficiaries, of which 2 million are enrolled in our own stand-alone PDP.

Though ESI sponsors its own prescription drug plans (PDPs), we also support many plan sponsors that have a direct contract with CMS via a prescription drug plan (PDP) or Medicare Advantage (MA-PD) benefit. We take an active and consultative role with these plan sponsors to ensure their Medicare solutions are comprehensive, compliant with regulatory requirements, and aligned with their beneficiaries' needs just as much as we do our own products. ESI strives to provide the best possible support and service to our plan sponsors and patients to ensure optimal performance. In that spirit, we respectfully submit the following comments for your review and consideration:

Attachment VI, Section I – Enhancements to the 2019 Star Ratings and Future Measurement Concepts – (Page 106): CMS proposes, after the 2019 Call Letter is finalized, to establish a Technical Expert Panel to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures.

> ***ESI Comment:*** *We support the convening of a Technical Expert Panel consisting of a broad array of program stakeholders—including Part D plans supporting both MAPD and PDP benefits, PBMs, providers inclusive of pharmacies and physicians, and beneficiaries—to evaluate the framework of the current CMS Star Ratings system. As the panel assesses the current methodology, it is critical that they consider revising cut-point and data collection time periods. Currently, final cut-points are not released until the end of the rating period. Modifying the methodology to develop pre-determined cut-points would empower plans to drive results towards established thresholds. To further these aims, ESI urges the panel to also consider modifying the data collection time periods so they are more reflective of a plan's current performance. For many metrics, data used to determine the next year's star rating is*

from the prior year; this not only fails to account for any improvements the plan may have achieved in the current year, but also does not permit plans to course-correct in any areas where performance may not be tracking toward targeted expectations—or be rewarded for such efforts in a manner that is closer to "real-time."

Attachment VI, Section I – New Measures for 2019 – Star Ratings:

Statin Therapy for Patients with Cardiovascular Disease (Page 107) - CMS proposes including the "Statin Therapy for Patients with Cardiovascular Disease" measure in the 2019 Star Rating, with a weight of "1."

ESI Comment: *We are generally supportive of implementing a measure addressing the use of statin therapy in patients with cardiovascular disease, and urge that such a tool be aligned with the measure as adopted and further amended by the National Committee for Quality Assurance (NCQA). ESI has concerns, however, that the proposed measure only seeks to record whether the drug was prescribed, and not assess the patient's adherence rate for actually taking the drug beyond the initial fill. We note that, per NCQA's website, that the measure may be updated soon to include such adherence measurements. Accordingly, ESI recommends CMS consider how this measure may overlap with current Part D star measures addressing adherence to the statin medications.*

Attachment VI, Section I – Changes to Measures for 2019 – Star Ratings:

Medication Adherence for Hypertension, Medication Adherence for Diabetes Medications (Page 109) - To align with the Pharmacy Quality Alliance's (PQA) measure specifications and to expand the data sources available for identifying enrollees with End-Stage Renal Disease (ESRD), CMS proposes excluding beneficiaries with ESRD from the measure.

ESI Comment: *We support this proposed change and CMS' goal for aligning the measure with PQA's. ESI also supports including additional data sources as appropriate that can more accurately identify beneficiaries with ESRD.*

MPF Price Accuracy (Page 110) - CMS proposes certain changes to this measure to factor in the degree and frequency with which PDE prices align with those shown on PlanFinder.

ESI Comment: *We support providing accurate pricing information to beneficiaries as they make important healthcare decisions, including choosing their Medicare Prescription Drug Plan. First, ESI reiterates our concerns however—as shared in previous comments to CMS on this measure—with regard to the inherent inaccuracies that are unavoidable regarding the time delay between pulling such data and it's posting on Plan Finder. Specifically, all reported data from plans are at best 3 weeks old once finally posted, and 5 weeks old at worst. Despite previously acknowledging drug price variability, CMS has not yet addressed the idea of advising PlanFinder users of this "lag" by adding the reporting dates to files and also noting prices are subject to change. ESI suggests that a more accurate pricing comparison would involve CMS comparing/cross-referencing the actual PDEs received from the plan to the prices reported for Plan Finder on the dates for which the pricing data was actually submitted.*

Secondly, the prices displayed on Plan Finder are for very specific reference NDCs that do not reflect the natural price variations existing between similar medications on any given day (or hour, even, in many cases). Normal market fluctuations alone create inconsistencies between what may be viewed on the Plan Finder and a PDE from a specific date. Accordingly, we urge CMS to provide disclaimers notifying beneficiaries

expect normal variation so that they are not misled into believing the displayed price is exactly the amount they should expect to pay consistently at the point of sale (POS).

Thirdly, ESI respectfully suggests CMS convene a stakeholder group tasked with developing more appropriate means to more accurately provide pricing data to beneficiaries, and we would be eager to participate accordingly.

Attachment VI, Section I – Removal of Measures – Star Ratings:

Beneficiary Access and Performance Problems (BAPP) (Page 112) - CMS proposes to retire the current BAPP measure for the 2019 reported star ratings. Instead, CMS proposes to modify the BAPP measure to include only Compliance Activity Module (CAM) data and move this modified measure to the display page for the 2019 Star Ratings.

ESI Comment: *We support retiring the current BAPP measure as a star rating. ESI opposes the inclusion of audit findings in the BAPP measure on the principle that not all plans are audited each year. Further, many audit findings are the result of highly targeted approaches and do not always reflect the plan experience of many beneficiaries. Because CMS has acknowledged that there is no correlation between plan audit performance and star rating performance, we strongly recommend CMS continue maintain this measure as on display only.*

With regard to the proposed modification to the current BAPP measure, ESI respectfully recommends that CAM data from July – June be used by CMS (instead of Jan – Dec) so that the data better aligns with actions related to the measurement year, and to accommodate inherent delays with publishing CAM data. Also, as a member of AHIP, we echo their recommendations that the BAPP measure remain on the display page until it has been fully evaluated/validated, and forthcoming introductions of such revised measures be subject to the future Star Ratings rulemaking process. At a minimum, ESI suggests CMS maintain this as a display measure for one additional year.

Attachment VI, Section I – Proposed Scaled Reductions for Appeals IRE Data Completeness Issues – Star Ratings (Page 114): CMS is proposing statistical criteria to reduce a contract's Star Rating for reporting data that is incomplete or lacks integrity using Timeliness Monitoring Project (TMP) data, but will also use multiple data sources whenever possible to assess IRE data completeness and the severity of any identified data deficiencies. Under the proposal, contracts would be subject to possible point reductions for data incompleteness if both of the following criteria are met: the calculated error rate is 20% or more; and at least 10 cases are projected not to be forwarded to the IRE within a 3-month period.

ESI Comment: *In concept, we support CMS utilizing a tiered approach to applying penalties for plans demonstrating a lack of data integrity. ESI respectfully suggests there is an opportunity to "level-set" with plans on CMS' expected results from use of TMP and also improve the training of auditors. We appreciate that TMP may indeed eventually become a way to ensure all contracts are treated fairly in light of the fact that not all are audited each year. ESI believes, however, that TMP is not quite ready yet to fulfill this aim.*

For example, ESI observes that the current scaling of IRE cut-points can drive smaller plans into situations where a five-star rating is unattainable even if they have only one IRE citation whereas larger plans with substantially more infractions can still achieve the highest possible rating. In other words, the current process favors plans with higher enrollment and more significant data integrity issues over lower enrollment plans with even just a single infraction. We believe this situation must be addressed before TMP is adopted as the "great equalizer"

among plans in this measure. Therefore, until the performance and evaluation standard can be fully defined and understood by both plans and auditors, we believe this data should not be used as a display measure or basis upon which to penalize plans.

In addition, ESI shares concerns raised by AHIP regarding CMS' policy that automatically downgrades rating scores to one star for non-appeals measures, and recommend CMS engage stakeholders in developing alternative approaches to current policy so as to ensure that severe penalties are not applied inappropriately. We hope CMS would agree that not all violations should be treated equally severely (e.g. when a data submission error is identified early, is not indicative of systemic deficiency, and is curable during the plan preview period).

Attachment VI, Section I –Potential Changes to Existing Measures – Medicare Therapy Management Program Completion Rate for Comprehensive Medication Reviews Measures. (Page 147): CMS proposes to adopt the PQA revision to the CMR for eligible patients with fewer than 61 days of continuous enrollment in the MTM program.

ESI Comment: *We fully support CMS revising the CMR calculation as updated by PQA.*

Attachment VI, Section I – Potential New Measures for 2020 and Beyond – Adult Immunization Measure (Page 150): For the Health Effectiveness Data and Information Set (HEDIS) 2019, NCQA will be building off from the adopted 2018 Pneumococcal Vaccination Coverage for Older Adults measure and evaluate four routine adult vaccinations: influenza vaccine; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria (Td) booster vaccine; herpes zoster vaccine; and pneumococcal vaccine. Accordingly, CMS is inviting stakeholder feedback on the feasibility, value of, and burden of making such a change to the data source.

ESI Comment: *We believe vaccine measures relying on Customer Assessment of Health Providers and Systems (CAHPS) survey responses do not accurately record actual vaccine administrations. Alternatively, ESI encourages CMS to use data from prescription drug claims or medical records for this measure as they are more accurate indicators of beneficiaries' receipt of vaccines.*

Attachment VI, Section I – New Medicare Card Project (Page 167): As the current Health Insurance Claim Number (HICN) will be replaced with a new Medicare Beneficiary Identifier (MBI) beginning in April, 2018 CMS is reminding stakeholders of the pending transition period during which either the HICN or the new MBI may be used to exchange data with CMS.

ESI Comment: *We respectfully request CMS confirm whether adjustment and/or deletion PDEs submitted with an MBI after 4/1/2018 will NOT reject for edit 660 (i.e. the Adjustment/Deletion PDE does not match the existing PDE record) when the accepted original record has the beneficiaries' HICN. Because HICN is a key field for DDPS processing in matching an original PDE to the adjustment/deletion record, ESI seeks to confirm whether DDPS will be accepting the records and performing a crosswalk back to HICN when an MBI is received, as CMS has the HICN on the original PDE for the beneficiary.*

The Appeals memo released on February 16th is requesting that plans continue to solely utilize HICN on the cover letter until the transition window ends. Solely using the HICN is in direct conflict with prior guidance that state HICN or MBI will be accepted during the transition period. We are requesting that CMS republish this memo noting that either HICN or MBI can be utilized on the Appeals or Redeterminations letter during the transition period.

ESI notes that CMS has released COB & BEQ changes that we believe did not align with previously released guidance—specifically, that the file contained MBI prior to April 1, 2018.

Additionally, the COB file layout changed to accommodate a new field for MBI. All guidance received up to this point has directed the industry to expect the existing HICN field to contain the MBI or HICN during the transition period, and that the existing HICN field will contain only the MBI after the transition period. Accordingly, we also request CMS confirm that there is no subsequent change in direction by adding MBI as an independent field.

Attachment VI, Section III, Part D – Formulary Submissions – (Page 193):

CY 2019 Formulary Reference File -

1. **Removing Infrequently Utilized Drugs:** CMS proposes revising the FRF after analyzing part D utilization and subsequently removing drugs that are found to be used infrequently:

   ESI Comment: *We welcome the opportunity to review the proposed revisions in the February file.*

2. **Introducing New Flexibility through Summer Formulary Update** – CMS proposes to offer a summer formulary update window with an updated FRF that allows the addition of drugs new to the summer release of the FRF, and allow negative changes on brand drugs if an equivalent generic or therapeutically similar drug is added to the summer FRF.

   ESI Comment: *Plan sponsors recognize the importance of a Summer Limited Window to make select changes to their "new year" formularies prior to the start of the year. However, the proposed delaying of this window until August may present difficulty for plan sponsors in producing and printing required plan materials including coding, formulary testing, and utilization management within required timeframes after the Summer Limited Window concludes and Conditional Approval is granted. Accordingly, we therefore respectfully request that CMS consider retaining the current Summer Limited Window for mid/late July.*

   Further, additional formulary submission windows provide benefits for both plan sponsors and beneficiaries by granting the former flexibility with formulary management, and giving the latter greater visibility into their drug coverage based on CMS-approved formularies displayed in PlanFinder. Per this Draft Call Letter, CMS also proposes both an enhancement-only window in the fall, as well as a new January submission window. ESI respectfully requests CMS consider the timing and potential benefits of these new proposed windows in concert with the proposal moving the Summer Limited Window to August, since we believe there may be some unintended complications.

   For example, if the Summer Limited Window is moved to August, adding an enhancement-only window in the fall may not provide additional benefits depending on their timing and spacing between them, and may in fact increase administrative/filing errors. Further, clarification is needed as to whether an updated Formulary Reference File will be proposed in support of this enhancement-only window. Lastly, if CMS elects to proceed with these proposals, we respectfully suggest CMS reconsider establishing the timing of this enhancement-only window in January, given that doing so only adds to the number of submissions made in the early part of the year with respect to the already substantial sponsor activities and deliverables required by Open Enrollment, plan benefit set-up, and testing that are also due during the same timeframe.

Change for CY 2019 Formulary Submission - Eliminating the non-extended day supply file:

ESI Comment: *We support retirement of the Non-Extended Day Supply supplement file and thank CMS for doing so.*

Expanding the Part D OTC Program – CMS proposes supplying plans with an "Over-the-Counter" (OTC) reference file for CY2019 that uses a proxy code to represent each unique drug ingredient, strength, route, and dosage form, but would not also include every possible branded OTC.

ESI Comment: *We applaud CMS' decision to standardize the OTC supplemental file submission for plan sponsors, but also ask for clarification as to whether CMS plans to release the OTC Reference file annually, or updated monthly with the Part D FRF.*

Attachment VI, Section III – Improving Drug Utilization Review Controls in Medicare Part D (Page 202):

Part D Opioid Overutilization Policy – In addition to improving formulary management, CMS expects sponsors to:

1. Retrospectively perform enhanced drug utilization review (DUR) to identify potential opioid overutilizers and provide appropriate case management aimed at coordinated care; and
2. Prospectively manage drug utilization by implementing real-time safety alerts at the time of dispensing as a preventive step to ensure prescribers are aware that potentially high risk levels of prescription opioids will be dispensed to their patients (concurrent DUR).

Additionally CMS seeks to propose new strategies for addressing opioid abuse in Part D by enhancing OMS, supporting PQA measures, implementing hard and soft formulary edits, limits on days' supply allowance, and other safety edits where other drugs of concerns may be used.

ESI Comment: *We are committed to reducing unnecessary prescribing, dispensing and use of opioids to help avoid beneficiary abuse and unnecessary hospitalizations while also ensuring appropriate access to these medications for those patients that need them. ESI has found—based on our substantial data analysis capabilities—that early interventions involving the patient, prescriber and pharmacy can also reduce abuse risk. We commend CMS' commitment to reduce abuse while assuring the safe use of opioids among the Medicare population, and recommend that future policies adopted will integrate with CARA requirements.*

As a member of the Pharmaceutical Care Management Association (PCMA), we support their comments on this topic but will not reiterate them here.

Opioid "Potentiator" Drugs – CMS proposes adding a concurrent opioid-gabapentin and -pregabalin flag to OMS and seeks input as to other potentiator drugs that should be added.

ESI Comment: *We support adding a concurrent opioid-gabapentin and -pregabalin flag to OMS, along with similar flags for "centrally-acting muscle relaxant" for incorporation into the current Part D Opioid DUR policy and OMS as possible "potentiator" drugs. ESI also reiterates the need for CMS to grant Part D plan sponsors greater flexibility to implement novel drug management programs to help address this crisis.*

Requiring Sponsors to Implement Hard Formulary-Level Cumulative Opioid Safety Edits at the Point of Sale – CMS seeks feedback on whether all sponsors have the capacity to implement hard edits at 90 MME as well as the 7 days' allowance proposal for 2019.

> ***ESI Comment:*** *We have consistently supported implementing a hard edit for years, and would be able to implement a change in the MME to 90 while also supporting a 7-day allowance for new starts. That said, such edits should not break therapy on current users.*

Implementing a days' supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME per day).

> ***ESI Comment:*** *We recommend the 7-day allowance be implemented for new starts only, since only the prescriber can determine the pain type for which the patient is being treated and this cannot be determined at the point-of-sale without stopping the claim from being processed entirely.*

Attachment VI, Section III – Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs (page 218): CMS proposes becoming the single source for transplant information and that plans utilize this information as the "best available evidence" for determining whether immunosuppressants are covered under Medicare Parts B or D.

> ***ESI Comment:*** *We agree that the proposed clarifications are very helpful and clearly state when Part D payment for immunosuppressant drugs will be made. In the past, timeliness of the data submitted was a significantly more important factor for plans to consider given that hundreds of thousands of dollars in PDE records would have had to be deleted based on information unavailable to the plan or the partnering PBM at the time of adjudication. The move to adjudicating based on the "best available evidence at the time" is a welcome change.*
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> *ESI encourages CMS to continue to improve the data available to plans for kidney transplants, as well as all other Medicare subsidized transplants as a source to be used when making claims payment determinations.*
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> *That said, we respectfully request additional clarification on how plans should factor physician supporting statements when making Medicare Parts B or D coverage determinations. ESI understands that in current practice, MARx indicators take precedence when available but, when not, that a physician's statement may be acceptable/determinative. This proposed "best available evidence" standard appears to conflict with the Medicare Manual's Chapter 18 instructions informing plans that a prescriber's supporting statement bears "great weight" in making such coverage decisions.*
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> *Addressing this issue at the POS is the most efficient approach that also fosters the best beneficiary experience. To support Plans' ability to offer the best service for beneficiaries in these situations, we respectfully request CMS provide them AND their delegated entities use of a reliable indicator on a file such as the TRR that can be used by PBMs as a "source for confirmation" for payment determination. ESI also recognizes that the MARx system also serves as a reference for plans to confirm payment determinations in these situations, but unfortunately access to the system is currently granted on a plan-by-plan basis, and is not made available to delegated entities like PBMs.*

As an alternative to permitting use of "reliable indicators," we urge CMS to consider granting Plans and their partnered administrators making payment determinations on their behalf access to the MARx system for such purposes. ESI believes granting these delegated entities access to the MARx system information to be an especially attractive solution since payment determination services are typically provided by entities managing hundreds of CMS contracts on behalf of contract holders.

*Lastly, we appreciate the clarification on use of the best available evidence policy when making payment determinations regarding inhalation DME supply drugs. ESI respectfully requests CMS also consider providing plans and their PBMs a mechanism with which to verify whether a beneficiary is in the Part A phase of LTC coverage***.**

Attachment V, Section III – Part D Mail-Order Refill Consent Policy – Solicitation for Comments (page 220): CMS seeks comment and data associated with mail-order auto-ship programs indicating actual improvements in adherence by patients resulting from automatic refills, information or data that rebuts concerns that such programs increase medication waste, and feedback on possible modifications to the current policy if it is determined a change is warranted accordingly.

ESI Comment: *We appreciate the efforts CMS has put forth to control fraud, waste and abuse (FWA) in the prescription drug benefit, and this request for input on balancing those needs with increasing member adherence and fostering high plan STAR rating performance. The "Exception for New Prescription Delivery (available to all Part D plan sponsors)" has largely accomplished those broader goals, and ESI believes beneficiaries will enjoy significant benefits from appropriately expanding Automatic Refill Prescription Delivery programs that are currently only available to EGWP sponsors.*

An internal analysis of data on our automatic refill program among our clients—including EGWPs—shows a 9.1% increase in adherence for members enrolling their maintenance medications into this option when compared against members utilizing our mail order pharmacy but not use the automatic refill program. Additionally, this increase results in higher plan adherence STAR ratings specifically for measures of Diabetes, Hypercholesterolemia, and Hypertension. Further, understanding the pressure CMS has received from other stakeholders not to expand use of automatic refills, we note that since 2014 ESI has received a total of 81 beneficiary complaints/grievances with regard to this program is ***unavailable to them in Part D outside of EGWP****. Some of the observations shared with us by beneficiaries that have experience with our program include:*

- *Ease of enrollment—it is voluntary and "opt-in" only*
- *Program applies only to refill/renewal medications, not new/initial prescriptions*
- *Beneficiary control over scheduling their prescription orders online regarding when they want/need their next order.*
- *Reminder notifications (not consent verifications) provided well in advance of shipping an order—that also serve to prevent gaps in access to medications that contribute to non-adherence*
- *Flexibility to dis-enroll from the program at any time (online or by phone)*
- *Beneficiary convenience—removal of obstacles that contribute to non-adherence, such as:*
    - *Saving time by not having to call in, go online, or travel to a pharmacy every time a maintenance medication refill/renewal is needed; and*
    - *Home delivery to ensure adherence in case they are unable to travel to a pharmacy (e.g. inclement weather, health conditions like the flu, etc.)*

ESI shares CMS' concern with waste that may be associated with unwanted or unneeded medication refills. Accordingly, we have guardrails in place to prevent any waste associated with this program. For example, the refill program operates in a 90-day cadence to ensure that a member never has more than (or less than) an 18 day supply on hand, and we communicate with them 10 days prior to processing an order to allow accommodation in the event that a patient needs to delay or cancel a fill/shipment.

In light of these benefits, in addition to EGWP sponsors only, we would recommend that all Medicare Part D plan sponsors have the ability to utilize an automatic refill program, as it empowers their beneficiaries to take advantage of the above features offered by an auto-refill program. Plans would continue to apply the refund, hospice and annual consent conditions that were set in place for the EGWP Plan Sponsor Exception back on 10/28/2013, so that:

- *A refund is promptly provided—and the prescription drug event (PDE) deleted—for any auto-shipped refill that the beneficiary reports as unneeded or otherwise unwanted;*
- *Plans promptly discontinue automatic delivery after receiving notification that a beneficiary entered a skilled nursing facility or elected hospice coverage; and*
- *The plan will confirm whether the beneficiary wants to continue in the automatic delivery program at least annually and upon receipt of a new prescription from a provider, even if the new prescription is a continuation of existing therapy.*

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Express Scripts appreciates the opportunity to comment on the draft CY 2019 Advance Notice and further appreciates consideration of our recommendations. If you have questions regarding our comments, please contact me at 202-383-7987 or sasantiviago@express-scripts.com.

Sincerely,

Sergio Santiviago
Director, Government Affairs
Express Scripts