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SUBMITTED ELECTRONICALLY

January 16, 2018

Hon. Seema Verma, Administrator
Centers for Medicare &
Medicaid Services, Department of
Health and Human Services,
P.O. Box 8016,
Baltimore, MD 21244–8016

Re: CMS–4182–P: 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:

Express Scripts appreciates the opportunity to submit our comments on CMS-4182-P, the proposed 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 (proposed rule). 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.

Towards furthering CMS' goals with respect to ". . . implement[ing] certain provisions of the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act," while also making changes that support innovative approaches to improving quality and also improve the CMS customer experience, we respectfully submit the following comments for your review and consideration.

Preamble Discussion: Section II(A)(11) - Medicare Advantage and Part D Prescription Drug Plan Quality Rating System:

ESI Recommendation: We appreciate the efforts CMS has put forth to drive continual improvements in healthcare quality and treatment outcomes in the program. The Star Ratings program has demonstrably contributed to improvements in patient adherence within key classes of medications while also decreasing use of high-risk prescription drugs. Though ESI supports much of what CMS proposes in this section, we offer the following feedback with regard to specific provisions below:

- Annual Flu Vaccine Metric: CMS describes the CAHPS survey as tool for probing those aspects of care for which consumers and patients are the best or only source of information for the provider, and for this metric it also serves as the primary data source for determining the rating. We respectfully disagree with this approach to the measure, and the assumptions underlying them. ESI views the CAHPS survey as neither the best nor only source of information available for use in this case since the beneficiary response rate to these surveys has traditionally been a very low percentage of possible participants. We

therefore suggest CMS instead use both medical and prescription claims data as they are both more holistic and reliable information sources from which to conduct assessments.

- SNP Star Reporting Level: For MAPD contracts having a mix of both SNP and non-SNP plans, ESI believes that "plan" level ratings may actually be a better reflection of true plan performance than the current metric. We note the SNP population is a unique population with singular needs, and also that the program already utilizes several SNP-specific measures. Accordingly, ESI suggests CMS investigate developing an alternative solution for the SNP population in addition to the current CAI adjustment—possibly even one that excludes these lives to account for the particular characteristics of these plans and their beneficiaries. We welcome any opportunity to engage CMS further on possible options in the future.

- PDP Contract Star Reporting Level: We respectfully urge CMS to continue reporting Star Ratings at the "contract" level. ESI believes reporting Star Ratings at the plan level would produce inaccurate results due to a lack of sufficient data—especially if a plan is too small to be measured based on its enrolled population. In addition, some metrics would require continued tracking at a contract level, otherwise the data collection would need to be adjusted to compensate. For example, call center phone numbers are shared and would not be tracked otherwise at a beneficiary level, and CAHPS sampling would have to be expanded accordingly. Continuing Star Ratings reporting for PDPs at the contract level therefore avoids having to address these concerns without sacrificing the measure's accuracy.

- Measure Weighting: ESI supports CMS' commitment to solicit beneficiaries' perspective as it pertains to their selected plan's quality, but cautions against increasing the relative weighting of CAHPS measures within the Star Rating and recommends keeping the current 1.5x multiplier. Currently, CAHPS measures represent approximately 16.8% of the overall star rating for MAPDs, and moving to a 3x weight as proposed increases the effect to 29.5% of the overall star rating. Since CAHPS survey populations are low, even a 100% response rate would represent a very small portion of the overall plan population. However—as noted previously—response rates for CAHPS surveys are generally poor, thus making them an unreliable indicator of member satisfaction that could distort the measure's overall accuracy.

- Data Integrity: CMS is proposing to apply a scaled reduction for data integrity issues involving multiple data sources. While ESI believes the scaled reduction proposal appears to be a reasonable one, we respectfully request that CMS share all simulated data testing the scaled reduction approach publicly. This would include, for example, the 2016 Industry-wide Appeals Timeliness Monitoring Project results on the 2018 IRE metrics performance in order to allow plan sponsors the opportunity to assess their specific impact resulting from the application of the proposed methodology.

Preamble Discussion: Section II(A)(12) – Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types -

ESI Comments: On principle, we acknowledge the responsibility and trust placed upon plan sponsors (and third party administrators, such as PBMs) to operate their respective part of the Part D program by Congress when it passed the MMA. This trust was codified in 42 USC §1395w-111(i), otherwise referred to as the "Non-Interference Clause," which prohibits the HHS Secretary—and therefore CMS from—interfering ". . . with the negotiation between drug manufacturers and pharmacies and PDP sponsors." While this provision does not permit each of these parts to operate without

regulatory oversight, it nevertheless is a key reason for the overall success of the Part D program because it indeed fosters what it was intended to: competition.

The non-interference clause not only spurs competition vertically and horizontally within the Part D program, but also brings about innovations that have introduced efficiencies, enhanced safety, and driven value for both beneficiaries and CMS. These innovations have largely come forth through creative benefit designs and negotiations between plan sponsors, drug manufacturers, and pharmacies. As CMS is fully aware, among the most popular developments among beneficiaries in recent years involves the introduction of preferred pharmacy networks—an innovation that has helped keep premiums well below predicted growth rates without sacrificing access to, or quality of care.

Unsurprisingly—indeed, to their credit—traditional retail pharmacies (chain and independent) have begun to explore incorporating new and innovative services to enhance their competitive positions between themselves, including limited specialty and mail order dispensing, etc. Contrary to misrepresentations by certain constituencies advocating for a return to pre-MMA days, ESI welcomes these efforts. In fact, we enjoy collaborating with these innovative pharmacies and including them in our PDP networks—but only *after* establishing that these providers are qualified, duly-licensed, and/or accredited to provide such services competently under terms that are consistently applied across our entire pharmacy supply chain. To put it more bluntly, we will not risk the safety of our patients—whether through our commercial business or Medicare—by permitting an unqualified, unlicensed, and/or unaccredited pharmacy seeking to expand their business by dispensing prescribed medicines without demonstrating the competence earned by their many peers who accept and meet such critical standards as a condition of joining our pharmacy networks.

Moreover, it is to plan sponsors' benefit to foster beneficiary access to a broad—but safe and high-quality—network of pharmacies offering an array of services in the settings they prefer. After all, ESI competes with other PDPs and PBMs for covered lives both in the standalone market and as TPAs to insurers and the self-insured. It would not behoove us to offer plans that fail to compete with those of other plan sponsors offering appropriate access to innovative pharmacy services. That said, we believe it is useful to address why there is a need for the licensing/accreditation standards such innovative pharmacies must meet to further illuminate why exploring any changes that alter current practices may invite unintended and/or unappreciated negative consequences to beneficiaries and the program.

At the risk of stating the obvious, we note there are significant differences between a retail pharmacy that provides *some* mail services and a mail order pharmacy offering *some* retail services. Mail order dispensing—whether in small or mass volumes—requires both technical and clinical expertise to ensure safe and proper handling/shipment. Likewise, most mail-order pharmacies are designed specifically for that purpose and do not often have walk-in capabilities, given the unique requirements for in-person dispensing at the retail counter. Specialty pharmacies have even more stringent standards to must meet due to the nature of the products they dispense, the more comprehensive clinical services necessary to accompany dispensing, and additional regulatory requirements mandated by FDA and drug manufacturers accordingly. While there are potential advantages for pharmacies to offer diversified and/or hybrid services beyond the traditional retail setting, they must not be pursued or achieved in a manner that sacrifices the clinical safety and quality standards other pharmacies specializing in any one particular format must otherwise meet.

ESI is concerned that the current proposal is too ambiguous to allow proper assessment and sharing of feedback to CMS on the potential ramifications of any future changes. We also believe that CMS' decision not to include specific definitions at this time is a tacit admission of awareness that the consequences—positive or negative—of such a radical policy shift will be significant to beneficiaries and the program. Though we foresee no positive outcome from making future changes along the lines contemplated in this section of the preamble, we caution CMS that any such future regulation

will fail to account for the inevitable unanticipated, negative effects on the pharmacy supply chain within the Part D program it will ultimately have.

Our fear in this regard is based not on the best intentions or competency of CMS to establish parameters and standards of reasonableness as to what constitutes retail, mail, and specialty pharmacy definitions. Rather, our concern arises out of a recognition that the principle purpose of the non-interference clause was to foster innovation, and in achieving this we have seen substantially beneficial effects in the program that were not otherwise anticipated during the program's inception. For example, the current preferred pharmacy networks so popular among beneficiaries today did not emerge in the form originally predicted at the time the MMA passed. That said, the hope such innovative products would emerge under the statute's framework if—in practice—its design to foster such novel ideas worked as intended *was indeed* contemplated by the legislation's drafters. As clinical, technological, and other unanticipated advances make their way into the healthcare industry in the future, the opportunities for unique solutions to be adopted will be driven by a competitive market that has the flexibility to address the evolving needs of patients and clients.

Therefore, by continuing along the proposed path we respectfully posit CMS risks at least two potentially serious, negative outcomes: 1. safety and quality standards may be weakened or otherwise circumvented; and 2. defining products and services in the present—where the pace of regulation can all but never keep up with rapidly changing innovations in the dynamic market we are currently experiencing in the pharmacy industry—will only hamper, if not shackle, development of future innovations to the detriment of beneficiaries and the Part D program.

ESI Recommendation: We therefore respectfully urge CMS not to pursue changing current definitions of pharmacies within the Any Willing Pharmacy context or otherwise. As noted in the above discussion, our overriding concern is that defining "down" standards or otherwise deferring to other sources intended only to broaden pharmacy access to Part D beneficiaries (who already enjoy access to pharmacy networks exceeding the strict TRICARE minimum standards) risks considerable harm to the very patients proponents of such changes claim they seek to assist. Further, we have seen instances where state standards are not enforced or monitored; therefore, retaining the ability to not only remove, but prevent the re-admittance of, fraudulent, wasteful or abusive pharmacies is a tool that protects Medicare beneficiaries.

As CMS cites anecdotal evidence from certain pharmacy constituencies as spurring this current concern, we offer the following actual examples where current policy allowing plan sponsors to contract with safe, high-quality pharmacies for PDP networks ensured protection of beneficiaries without sacrificing access to care:

- Example #1 – Our internal Fraud, Waste, and Abuse (FWA) team investigated three pharmacies owned by the same person based on the identification of suspicious billing patterns as well as the receipt of numerous complaints from patients who received prescription medications they did not order. At the conclusion of the investigation, which included a review by ESI's Pharmacy Disciplinary Action Committee (PDAC) and resulting in a finding of fraudulent practices, all three pharmacies were terminated from the Express Scripts Pharmacy Network Shortly thereafter, the pharmacy owner attempted to re-join ESI's network using a different name. This attempt to falsely credential was identified and the application was denied—thereby preventing this unscrupulous pharmacy owner further opportunity to defraud Medicare and beneficiaries.
- Example #2 – ESI's FWA team investigated another pharmacy based on the identification of patterns of suspicious billing, specifically involving drugs that are commonly used in fraudulent practices. As in the previous example, the pharmacy was terminated from the Express Scripts Pharmacy Network at the recommendation of our PDAC after reviewing the FWA team's finding that significant fraud had occurred. Since termination, the

pharmacy has made eight separate attempts to regain entry back into ESI's network, each time caught and denied after misrepresenting themselves in their applications.

Preamble Discussion: Section II(A)(13) - Changes to the Days' Supply Required by the Part D Transition Process -

CMS proposes two changes to current requirements for Part D sponsors to provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on the prescription drug plan's formulary transition supply requirements for Long-Term Care (LTC) beneficiaries. The first would shorten the required transition days' supply in the LTC setting to the same supply currently required in the outpatient setting. The second proposes a technical change to the current required days' transition supply in the outpatient setting to be a month's supply.

ESI Recommendation: We support these proposed changes and recommend CMS adopt them in the final rule.

Preamble Discussion: Section II(A)(14) - Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes -

In this section, CMS proposes to provide Part D sponsors with more flexibility to modify drug formularies during the current plan year under certain circumstances. Specifically, plan sponsors meeting all requirements may remove brand name drugs from a plan formulary—or make changes in their preferred or tiered cost-sharing status—when those drugs are to be replaced with therapeutically equivalent newly-approved generics, rather than having to wait until the current direct notice and formulary change request requirements have been met. Additionally, plan sponsors would be allowed to make those specified generic substitutions at any time during the year—including within the first two months following the start of the plan year. Related proposals clarify notice requirements in light of the proposed changes to the midyear formulary change process.

ESI Recommendation: We enthusiastically support CMS' efforts to provide Part D sponsors with greater flexibility to make mid-year formulary changes, and urge adoption for the final rule. ESI has long opposed the connotation that characterizes attempts to incentivize therapeutically-equivalent generic drugs through tiering designs while removing/dis-incentivizing more costly brand drugs as effecting a "negative" formulary change. To the contrary, that availability of new A-B rated generic equivalent drugs affords plan sponsors the opportunity to safely and effectively save/stretch drug spending for beneficiaries and CMS without sacrificing the quality of care provided is a positive development—even if technical terminology for formulary additions and subtractions are not meant to assign "values" to these terms as such.

Preamble Discussion: Section II(A)(17) – Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale –

In this section of the preamble, CMS reports that—based on collected DIR data—price concessions obtained by Part D sponsors over brand-name drug makers and pharmacies through voluntary negotiations have grown significantly over the last five years. Further analysis showed that ". . . manufacturer rebates have grown dramatically relative to total Part D gross drug costs each year since 2010," and that pharmacy price concessions ". . . have grown faster than any other category of DIR received by sponsors and PBMs and now buy down a larger share of total Part D gross drug costs than ever before."

While acknowledging that beneficiaries "may" see the benefit of these price concessions through lower monthly premiums, CMS raises a concern that applying them in this way nevertheless does not allow a beneficiary to see the benefit of such price concessions at the retail point of sale (POS). Accordingly, CMS suggests that by not otherwise applying the concessions at POS, the "negotiated"

price reported on the PDE is therefore neither fully transparent nor representative of actual drug costs to the beneficiary and may have ". . . a negative effect on the competitive balance under the Medicare Part D program."

Specifically, CMS asserts that the trade-off from applying manufacturer and pharmacy concessions to lower premiums results in a beneficiary not gaining the benefit of ". . . a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug." CMS goes on to further allege that the application of concessions to premiums vs. lower costs at POS means—*ominously*—that shifting costs and plan revenues in this heretofore acceptable fashion via end of year DIR reporting now somehow "games" the Part D Payment Methodology, and is thus evidence that ". . . sponsors may have distorted incentives as compared to what we intended in 2005."

Hence, CMS has issued an RFI in this proposed rule soliciting comments on the effects—positive and/or negative—on the notion of ". . . requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale." Moreover, CMS implies that rulemaking on this proposal is forthcoming regardless of any feedback received that may recommend against it; we offer our comments below on this RFI in the hopes that adopting it is not yet a foregone conclusion.

ESI Recommendation: While we echo and support the detailed comments offered by our trade association, PCMA, in vigorously opposing this proposal we will not reiterate those arguments here. Instead, our comments will focus on strongly urging CMS not to proceed with any future rulemaking that *mandates* plan sponsors include a minimum percentage of manufacturer or pharmacy price concessions at the retail POS across *all* plan offerings. As previously discussed in our comments on the AWP section in the preamble, ESI firmly believes that one of the primary reasons for the ongoing success and popularity of the Medicare prescription drug benefit is the flexibility afforded plan sponsors to develop innovative plan designs that go beyond what CMS may have originally intended over ten years ago.

While we share CMS' interest in finding ways to drive value to beneficiaries and reduce their out of pocket costs in light of the ever-increasing cost of branded drugs, we caution that what is contemplated in this RFI will have far reaching impacts on the very fundamentals of the program as we now know it—that may result in unintended, unanticipated, and potentially harmful consequences for beneficiaries and CMS.

In light of this potential risk to the over forty million enrollees in the Medicare prescription drug benefit, ESI proposes that to the extent CMS elects to proceed with testing this concept, that it do so via the pilot process, or by otherwise giving plans sponsors the *option* to pursue this benefit design—subject to any new benefit design rules subsequently promulgated—rather than mandate it across all plan offerings. This way, all stakeholders in the program—beneficiaries, plan sponsors, pharmacies, drug manufacturers *and* CMS—can respond to the market for such products while still maintaining the "tried and true" benefit for those enrollees who prefer their current options. Moreover, such an approach would have the benefit of allowing beneficiaries to "vote with their feet," and ensure plan sponsors offer products that meet what the market demands.

It is this freedom for plan sponsors to respond to market needs—again, largely provided for by the non-interference clause—that has spurred innovations like preferred pharmacy networks that not only ensure lower out-of-pocket costs for beneficiaries, but ensure high quality care by rewarding pharmacies who meet more demanding performance standards. "Pay for performance," and "value based payment" are concepts that have emerged in the Medicare prescription drug benefit due to the highly competitive nature of the market, and the push for offering innovations that enable plan sponsors to differentiate themselves from others. Thankfully, CMS has recognized the role voluntary price concessions negotiated with pharmacies has played in describing how such features

came about: "Such price concessions are negotiated between pharmacies and sponsors or their PBMs, again independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM."

As noted by CMS, plan sponsors are not currently forbidden from offering POS rebates to beneficiaries; the industry migration towards keeping monthly premiums low as an alternative is a result of beneficiary demand. Current and potential enrollees have made clear over time that maintaining low premium costs is the single most important criterion cited for choosing between plan options. Over the evolution of the program, plans have recognized this and responded accordingly, keeping annual rate increases year-over-year as flat as possible to keep up both with their competitors and beneficiary demands. Again, private, voluntary negotiations with drug manufacturers have enabled plan sponsors to meet these needs.

Manufacturers, recognizing that low premium prices are of critical importance to prospective enrollees, negotiate arrangements with plan sponsors enabling premium stability via the process described by CMS: "[r]ebate amounts are negotiated between manufacturers and sponsors or their PBMs, independent of CMS, and are often tied to the sponsor driving utilization toward a manufacturer's product through, for instance, favorable formulary tier placement and cost-sharing requirements." Thus, in return for providing significant price concessions to plans that enable lower premiums year over year, manufacturers see greater utilization of their products—where therapeutic substitutions are clinically appropriate, of course—rewarding value and lower cost medications without sacrificing effectiveness or safety.

Further, ESI believes mandating plans share a minimum percentage of negotiated price concessions will not present a consistent advantage to all beneficiaries. Since not all drugs have rebates, beneficiaries utilizing those drugs will pay a higher premium without recognizing *any* POS savings. For example, while it is possible to obtain a 50-60% rebate on an insulin product and direct a portion of that to the POS to reduce a beneficiary's out of pocket cost, the same cannot be said for other, branded insulins or oncology drugs that offer no such rebates. While plan sponsors could blend any rebates gained across all drugs, the value passed on to the members is minimal, and would fail to offer beneficiaries true transparency into a particular drug's cost as well.

With regard to benefit and cost transparency, we also note that the current approach of reporting rebates as DIR does *not* prevent transparency. As CMS is fully aware, reported DIR is taken into consideration in future bids, meaning actual negotiated rebates are eventually realized and taken into consideration in the bid development. Mandating POS rebates could also have significant impacts to the competitive landscape as it adds negotiating leverage for drug manufacturers with plan sponsors, because it will be easier to "reverse engineer" drug pricing rebates offered by other drug makers and potentially the differing amounts collected by plan sponsors. By introducing imperfect or asymmetric information weighted more heavily towards drug manufacturers, PBMs will thus be at a disadvantage and our ability to negotiate could be significantly impacted—and diminished. The only stakeholder gaining from such program changes would be drug manufacturers.

While it remains unclear at this time as to what the precise increases in costs to beneficiaries and the program will be given the lack of specificity as to how a new POS rebate requirement would be implemented, we appreciate that CMS acknowledges those costs would not be reduced if adopted, but rather, *increased*. CMS' own estimates on the costs of mandating rebates from drug maker and pharmacy price concessions be applied at the POS would increase beneficiary premiums by $23.8 billion and $5.7 billion, respectively, while costing taxpayers $82.1 billion over the next ten years. We fear that—depending on the implementation details of any future rules—CMS' increased cost estimates may potentially be conservative.

Again, for the foregoing reasons ESI respectfully urges CMS not to mandate all plan sponsors include a POS drug rebate across all plan offerings and instead—if electing to proceed with evaluating a new approach to implementing one—permit plans the option to participate in a pilot testing the concept.

Preamble Discussion: Section II(B)(2) – Reducing the Burden of the Compliance Program Training Requirements -

This section proposes removing current provisions requiring Part C and D plan sponsors use CMS-developed compliance training programs for appropriate internal personnel in addition to their first-tier, downstream, or related entities (FDRs)—while continuing to hold sponsors responsible for any compliance failures committed by those FDRs. CMS' intent is to let plan sponsors and their contracted FDRs develop their own compliance training programs.

ESI Recommendation: While we understand some stakeholders will appreciate this proposed flexibility, we find it unnecessary and respectfully request CMS withdraw this proposal or, if finalized, still allow those sponsors who are satisfied with the current compliance training program to continue using it. In our experience, ESI has not found this requirement to be burdensome—unduly or otherwise—to ourselves or our contracted FDRs. To the contrary, we have found that using CMS' standard training *simplifies* the process of fulfilling the compliance training requirement. Were CMS to adopt this proposal as written, we see at least two potential issues of concern:

First would be that some plan sponsors or FDRs may incorrectly interpret this to mean compliance training is not required, thereby introducing uncertainty into what is now a clear direction. Second, without a standard program in place for reference and use, plans would be required to review each compliance training program employed by an FDR to ensure it meets CMS' standards and thus adding a new and substantial administrative burden. For these reasons, ESI reiterates its recommendation that CMS continue producing a standardized program as an option for those plan sponsors and FDRs who prefer to use it. Where sponsors then choose not to use the CMS-supplied program, we would support the proposal that the plan be held accountable for their FDRs meeting the compliance training requirement.

Preamble Discussion: Section II(B)(4) – Revisions to Timing and Method of Disclosure Requirements -

Plan sponsors are currently required to disclose detailed information about the plans they offer to their enrollees at the time of enrollment and at least annually thereafter. These disclosures are to be directly provided to enrollees in physical (i.e. paper) form within a prescribed timeline. CMS is proposing the following changes: 1. require plan sponsors to provide the aforementioned information by the first day of the annual enrollment period instead of 15 days before; and 2. rather than mandate plan sponsors provide hard copies of these annual notices, instead post them on their respective websites within the proposed deadlines, and only mail hard copies to enrollees *upon request*.

Forty-two million of the fifty-nine million Medicare eligible individuals are enrolled in Medicare Part D, and an Explanation of Benefits (EOB) document must be generated for each when they fill a prescription. Further, it is estimated that ~80% of Medicare enrollees utilize their prescription drug benefit, and in a majority of cases to obtain chronic medications. Assuming this 80% receives an EOB on a monthly basis, there are 403 million printed EOBs produced (at $1.75 each) in a given year at a total cost of $705 million. Converting to an electronic communication for EOBs would cut this annual cost by 50% or more.

Growing numbers of Medicare-eligible members enrolling in plans today are engaged, ready, and open to receiving materials electronically. Doing so not only saves the program money on mailing

costs, but also promotes a great member experience that further allows plans to engage beneficiaries on novel efforts to maximize better health outcomes.

ESI Recommendation: We enthusiastically support these proposed changes and recommend CMS adopt them in the final rule. Further, ESI strongly encourages CMS move to make electronic communication the new default process over paper, but still allow beneficiaries preferring print to continue receiving it upon request. We would also welcome an interim step whereby members could opt in to all or some materials currently being delivered in print.

What is most encouraging about replacing print with electronic communications and realizing these savings for beneficiaries and the program now is that it can be accomplished fairly simply by allowing sponsors to collect and use additional beneficiary contact information through the enrollment application process.

Preamble Discussion: Section II(B)(6) – Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations –

CMS proposes to change the timeframe for issuing decisions on Part D payment redeterminations and payment requests at the Independent Review Entity (IRE) reconsideration appeal level from seven to 14 calendar days from the date that the plan sponsor receives the request.

ESI Recommendation: We support this proposal and thank CMS for acknowledging that providing plan sponsors additional time to adjudicate these redeterminations and reconsiderations will provide a better beneficiary experience overall.

Preamble Discussion: Section II(B)(10) – Part D Prescriber Preclusion List –

Acknowledging the significant difficulties encountered so far in seeking to implement section 6405(c) of the Affordable Care Act (ACA)—requiring that prescriptions for covered Part D drugs may only be adjudicated if prescribed by a physician enrolled in the Medicare program—CMS is proposing a different approach that it hopes will more effectively fulfill the ACA's requirements. Specifically, CMS seeks to focus on preventing Part D coverage of prescriptions written by prescribers who pose an elevated risk (i.e. of committing FWA) to Medicare beneficiaries and the Trust Funds.

In essence, CMS will develop a preclusion list that will determine which prescriptions cannot go forward; this approach will not require prescribers to enroll with Medicare, and plan sponsors will likewise not be required to "validate" the prescriber's Medicare enrollment status against a positive enrollment list. Regrettably, CMS' mandate that plan sponsors provide provisional fills to initially denied prescriptions—a holdover from previous attempts to implement the ACA provision—reemerges in the current proposal as well.

ESI Recommendation: We appreciate and generally support CMS' new approach that disposes of the greatest weakness of the previous proposal—promoting Medicare enrollment among prescribers neither inclined nor interested in doing so. If the preclusion file is designed and implemented to work as exclusion lists function today, ESI agrees this solution circumvents this weakness in the original approach, and supports its implementation. It is disappointing, however, to see provisional fill remain in the new proposal; we believe this requirement is no longer necessary and will be confusing to members while adding needless complexity to the benefit.

Accordingly, ESI respectfully recommends CMS withdraw the provisional fill requirement in the final rule. If CMS proceeds with implementing this requirement however, we urge the establishment of a continuing dialog with industry partners on implementing the provisional fill functionality, including the setting of an "active date" no sooner than 8 months *after* a production

file is made available, thoroughly tested, and the functional assumptions around the file are communicated to the industry.

We question the need for provisional fills since the concept itself was intended to address the disruption expected from implementation of the original approach which was itself reliant on requiring all prescribers enroll in Medicare. The use of a preclusion list will limit potential beneficiary disruption significantly because CMS will establish the rules by which prescribers find themselves on it. Moreover, placement on the preclusion list will not be a function of prescribers failing to enroll but of matching criteria developed and administered by CMS. Further, the functionality CMS will employ to develop and implement this preclusion list may be done similarly to other excluded provider lists such as OIG/GSA lists—thus potentially bestowing consistency to member and provider experiences once established.

ESI also notes that allowing a provisional fill is inconsistent with how excluded providers are currently handled; that is, when an excluded provider submits a claim it is rejected at the POS with no override or additional fills provided. CMS contemplates that the provisional fill would allow the beneficiary an opportunity to find a new provider without interrupting access to prescribed medications. Although provisional fills would likely reduce such access disruptions for beneficiaries, our concern is that potential beneficiary confusion associated with the conflicting messages (i.e. "prescriptions from that particular provider can no longer be filled in the future, but it's okay just this once") may only delay the disruption until the beneficiary seeks to refill the prescription at issue. At which point, the disruption may be greater to the beneficiary because the delay in addressing the invalid prescription at the outset potentially risks non-adherence to the necessary medication while seeking a non-excluded prescriber to issue a substitute order.

Further, provisional fills raise safety concerns that may not have been anticipated by CMS. For example, providers on the preclusion list would likely have already been notified by CMS of that status, potentially several times. Put simply, the precluded provider is aware of their status yet continues to see Medicare patients and issue prescriptions for them. Whatever the motivation for providers continuing these practices in light of their status or the rationale meriting CMS precluding them in the first place, beneficiaries are subjected to risk. For example, what if the prescription issued involves controlled substances/opioids? A mandatory provisional fill assumes the script is clinically valid when it may not be and may undermine efforts to control dispensing of these high risk drugs.

ESI therefore encourages CMS to adopt functionality that is similar to how exclusion lists function today. Though the industry has implemented exclusion lists such as the OIG/GSA lists, questions of interpretation remain that must be addressed before this new preclusion list can be implemented:

- Given the effective date for this requirement is 1/1/19, we anticipate a fully functional production file is not likely to be provided to plan sponsors in time for full testing across various scenarios such as Transition periods and Coverage Reviews by that date. Will CMS acknowledge flexibility on full implementation may be necessary accordingly? Issues to be accounted for include:
    - Plan sponsors will need to be given sufficient opportunity and guidance to clearly understand and use the new file layout, including how each field is to be interpreted, and how the file may change over a given time period.
    - Where there may be conflicts between the preclusion file and other "sanction/exclusion" files, CMS must clearly designate the order of precedence for application. That is, would the presence of a prescriber on any of the several lists take precedence over not being included on others—thereby resulting in a claim denial under Part D?

- Will the range of providers defined as "in scope" for purposes of complying with the requirement be made clear for purposes of implementing the adjudication logic? By way of illustration, would providers—such as pharmacies—under MAOs be designated as "in scope" for this requirement? If so, CMS must provide clear instructions for sponsors to adjudicate claims (or not) involving situations where a precluded pharmacy is in a position to fill a prescription for a non-precluded prescriber.

- Lastly, we urge CMS to clarify for plan sponsors and prescribers that it would handle any appeal requests directly rather than thorough plans, given it is the agency that gathered and acted on the information that landed the prescriber on the preclusion list in the first place. ESI respectfully suggests CMS implement a process for notifying prescribers of a date after which adjudicators will stop their prescription claim processing.

Section II(A)(1) – Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions:

ESI Comments: Generally, ESI finds CMS' proposed requirements implementing CARA's provisions to be both reasonable and practical interpretations of the statute. We have long advocated for authority from CMS to lock plan enrollees into—and out of—both pharmacies and prescribers in situations where FWA are clearly occurring with respect to controlled substances—and opioids in particular. ESI cautions however that despite CMS' best efforts, open questions remain as to how plan sponsors are to treat members who challenge their lock-in designation. Given that the proposed rules direct such challenges be treated as an exception request, it remains unclear under what criteria/situations the exception request should be reconsidered or granted by the plan sponsor, respectively. Broadly speaking, we urge CMS provide plan sponsors significant latitude in operating their respective programs given our experience operating such plans in the commercial space and—most especially—to permit us to tailor our restrictions to fit the needs of each individual's case.

Before moving on to our comments on the specific provisions included in this section of the proposed rule, we wish to share with CMS information about our innovative approach addressing the opioid crisis for our commercial clients that we believe could be applied or adapted for use in the Medicare program. While recognizing the work done so far addressing opioid utilization among Medicare beneficiaries, we respectfully believe more can still be done for this population. On January 11th of this year, ESI published results on the performance of its Advanced Opioid Management Solution(SM) first introduced for commercial clients in the spring of 2017.

In the first 90 days since launching the program on September 1, 2017 ESI observed a nearly 60% reduction in the average days' supply for patients receiving an opioid prescription for the first time; from 18.6 days' supply per prescription claim *before* the program's launch, to 7.5 days' supply per claim *after* the program's start. We believe similar results can be attained in the Medicare population, but to do so, plans would have to be required to adopt and submit to CMS a 7-day limit on new prescriptions—a practice that is consistent with the CDC's guidelines on opioid use. We welcome further discussion of our initiative and our recently published results with CMS when convenient.

Additional discussions and recommendations on specific CARA implementation provisions follow below:

- **§423.100 Definitions:**

  - Exempted Beneficiary, Subsection (2) re: LTC Beneficiaries**:** Our concern lies not with regard to the definition of a Part D beneficiary enrolled in a LTC facility, but

rather the means by which plan sponsors will be able to identify such beneficiaries in a timely and accurate manner. While quarterly LTI reports may serve as a reference, they often provide dated and therefore potentially inaccurate information.

ESI Recommendation: To ensure continuity of case-management and safe treatment for locked-in beneficiaries who then move into an LTC facility, CMS must allow restrictions to remain in place and effective until/unless an appeal is made to the plan.

- **§423.153 Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs):**
  - (f)(4)(i)(B) – Requiring Prescriber Approval of At-Risk Beneficiary Lock-In Status: While the statute provides that a plan sponsor may not engage an at-risk beneficiary into a lock-in program without obtaining agreement from the beneficiary's prescriber first—thereby preventing effective case-management from proceeding—both the statute and NPRM do not speak to whether the plan sponsor may in any way share this disagreement with the HHS Secretary.

    In addition, most at-risk beneficiaries who qualify for prescriber/pharmacy lock-in receive prescriptions from multiple prescribers (e.g. doctor shopping). We respectfully request CMS clarify that plan sponsors be allowed to proceed with locking in an at-risk beneficiary to a single prescriber and pharmacy in situations where multiple prescribers disagree on whether such actions are appropriate—provided one of the them approves. We believe such an interpretation is permissible under the statute and advances the intent of Congress to aggressively address opioid abuse.

    Moreover the alternative interpretation, whereby a plan sponsor would need to obtain an agreement/approval from each prescriber would significantly undermine the timeliness and effectiveness of the lock-in program.

    ESI Recommendation: While we do not anticipate prescribers disagreeing or otherwise refusing to "verify" a beneficiary's "at-risk" status as determined by a plan sponsor, ESI suggests CMS develop some means by which it can track any such occurrences in the event such data may prove useful for evaluating the effectiveness of the current program's design. Additionally, in situations where at least one of several prescribers involved with a beneficiary's care agrees with a plan sponsor's determination of his/her at-risk status, the plan sponsor may proceed with limiting access under the terms provided in this rule.

  - (f)(4)(iv)(A) – 6 Month Delay Prior to Locking-In At-Risk Beneficiary: ESI vigorously opposes the imposition of a 6 month waiting period delaying "locking in" at-risk beneficiaries. The proposed delay period is not required by the statute, and will so significantly hamper the effectiveness of this new policy that it approaches subversion of Congress' intent. We respectfully remind CMS the end goal of CARA is to address medication abuse and promote patient safety in the Part D program, and that timely intervention is intended to be the means for accomplishing that goal.

    It is critical that at-risk beneficiaries be enrolled in lock-in programs as soon as possible in order to improve coordination of services and address potential prescription drug abuse. For high-risk patients, our considerable experience operating lock-in programs for commercial insurers shows that prompt intervention

after identification affords plan sponsors the opportunity to address these beneficiaries *before* developing long-term dependence and addiction to opioids. Moreover, acting quickly after identifying an enrollee's at-risk status also enhances coordination of high quality care for the locked-in beneficiary.

The likelihood of successfully treating at-risk patients through the lock-in concept depends upon how quickly patients are identified and connected to an intervention. Without timely intervention, patients will continue to inappropriately utilize opioids, putting themselves and/or others at risk of not only abusing opioids, but potentially death. A 6 month waiting period defeats the purpose of the lock-in program by undermining the premise of timely intervention being critical to successfully treating at-risk beneficiaries.

The 6 month delay also adds considerable administrative complexity and implementation burdens both for the at-risk beneficiary's current plan sponsor, but also—potentially—for a subsequent plan sponsor. Depending on when during the calendar year a beneficiary presents or is identified by a plan sponsor as being at-risk of abusing opioids, the 6 month period may conceivably extend into a future plan enrollment season and, where the beneficiary so elects, into a subsequent plan year under a new plan sponsor. Given the numbers of individuals aging into Medicare daily, the 6 month notice would prevent timely intervention and likely encourage at-risk beneficiaries to simply change plans each year. While the statute provides for notification from a previous plan to a subsequent plan of an enrollee's "at-risk" status, the 6 month delay needlessly invites administrative complexity and introduces opportunities for these beneficiaries to "slip through cracks."

Allowing lock-in programs to intervene on a timely basis also reduces diversion of controlled substances both within and beyond the Medicare program. If the proposed delay is adopted in the final rule, at-risk beneficiaries (and their potential enablers) will potentially have 6 months to continue acquiring supplies of opioids from multiple prescribers and/or pharmacies for the purposes of stockpiling for themselves or diversion to others for further abuse.

ESI Recommendation: We urge CMS withdraw this proposed 6 month delay preventing lock-in of a beneficiary duly identified as being at-risk of abusing opioids. Beneficiaries are given ample opportunities to appeal their designation under the statute and NPRM, along with the process by which he/she may select their prescriber or pharmacy.

- (f)(5)(ii)(C)(*2*) – Initial Notice to a Beneficiary: ESI has concerns with the proposed requirement that plan sponsors must provide "[a] description, of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access." Plan sponsors and their third-party administrators (TPAs) do not have ready access to such information, and, in the case of plan sponsors operating in multiple states (within which numerous communities have varying access to resources addressing prescription drug abuse), the challenges of providing accurate descriptions of available resources represent a significant administrative burden that also bears potentially negative consequences for patients in need who are provided dated, incorrect information.

  ESI Recommendation: Given that CMS—and HHS more generally—has ready access to the information this proposed provision seeks to provide, we recommend instead that a template be provided by the Centers to plan sponsors

for distribution to enrollees that includes the necessary information relevant to the applicable PDP region.

- (f)(6) Second Notice – The Second Notice requirement should only pertain to the lock-in program. CMS should retain the current notice protocols for drug-level restrictions implemented as part of the existing OMS process.

  ESI Recommendation: CMS provide model templates that include all relevant information (i.e. - standard national resources available to beneficiaries). Draft templates should be released for sponsor/industry comment prior to CMS finalizing.

- (f)(12)(ii)(A) – Treating a Pharmacy with Multiple Locations as One Pharmacy:

  ESI Recommendation: We have observed that a typical at-risk member engaging in doctor and pharmacy shopping behavior does not often go to the same pharmacy chain, though we have seen instances where prescriptions are filled at pharmacies with multiple locations. In those instances, the pharmacists/techs may not be checking the patient's prescription history or the state Prescription Drug Monitoring Program (PDMP)—if the state permits pharmacists to do so. In addition, pharmacies with multiple locations (who do not self-identify as chain stores, per se) may not necessarily utilize shared systems, policies, procedures that might otherwise prevent such varied responses in these situations. Given these circumstances, ESI recommends that CMS not adopt its proposal to treat pharmacies with multiple locations as a single pharmacy, and instead continue to support current FWA programs that evaluate these cases individually. We also note that restricting an at-risk member to a single location accordingly may allow the pharmacist(s) at that location to develop a relationship with the member that may lead to enhanced quality of care.

- (f)(14)(ii) – Termination of Identification as an At-Risk Beneficiary: We are concerned that automatic termination of lock-in and at-risk designation after 12 months sets an artificial and arbitrary limit that fails to consider whether clinical evidence at hand demonstrates the beneficiary is making the progress necessary to terminate status or not. We are also unsure why CMS believes this step is necessary when the statute does not call for such a limit. Moreover, this proposed duration limit significantly weakens the ability of this potentially powerful tool to address the opioid abuse crisis. Ultimately, we believe imposing this arbitrary limit will lead to mismanagement of opioids in the time that it takes to review and continue or put another restriction in place.

  ESI Recommendation: We respectfully request CMS withdraw the 12 month mandatory termination of At-Risk beneficiary status altogether. We note first and foremost that limiting the beneficiary's access to one prescriber and pharmacy (of their preference) does not limit access to care or the medications of concern; lock-in only limits the number of *sources* from whom he at-risk beneficiary may obtain them. The statute also provides that both prescribers and the beneficiary are permitted to appeal such status at any time. Accordingly, ESI believes the restrictions should remain in place for as long as the plan sponsor's case management team and the at-risk beneficiary's prescriber(s) determine it is appropriate.

Other Provisions of the Proposed Rule:

- **§423.160 Standards for Electronic Prescribing:**
    - (b)(1)(v) – Standards On or After January 1, 2019: ESI applauds CMS' recommendation to move forward with adopting SCRIPT version 2017071 in the 2019 plan year. The improvements made in this standard between v10.6 and v.2017071 are vast and will—once users and developers work through typical system bugs—further both CMS' and the industry's goal of improving patient care through the adoption of positively evolving technologies.

      ESI Recommendation: We caution CMS, however, that such migrations to new electronic standards typically encounter challenges—both those foreseen and unanticipated. Therefore, we respectfully request that the timeline for implementation of—and full transition to—SCRIPT v.2017071 be extended as needed to allow for necessary development, thorough internal and end-user testing, certification processes, and training of staff to ensure minimal disruptions for beneficiaries, prescribers, pharmacies, plan sponsors and CMS. Accordingly, ESI aligns with the NCPDP's recommendation of a transition period lasting no less than 24 months from the final rule's effective date before fully retiring v.10.6. We also suggest adding a voluntary adoption phase beginning when the final rule's provisions are effective. Lastly, to avoid opportunities for significant and unforeseen disruption occurring during the onset of a new plan year, we also request CMS not schedule the final regulatory compliance date during the months of December or January.

- **§423.265 Submission of Bids and Related Information:**
    - (b)(2)(ii) – Exception to Requirement of Substantial Differences Between Bids: ESI appreciates CMS' proposed change giving plan sponsors flexibility to submit enhanced bid submissions that do not reflect the substantial differences relative to any of its other enhanced bid submissions as previously required.

      ESI Recommendation: We support this change, and encourage CMS to formally adopt it in the final rule.

- **§423.578 Exceptions Process:**
    - (a) – Requests for Exceptions to a Plan's Tiered Cost-Sharing Structure: We find that the proposed section simplifies and clarifies CMS' expectations with regard to tiering non-preferred generics to preferred generics and, non-preferred brands to preferred brand tiers, respectively. We hope CMS can confirm this interpretation and consider providing updated examples for reference.

      ESI Recommendation: While the exceptions process is simplified, we respectfully offer the following suggestions and additional items for consideration:

        - We support exempting the specialty tier from cost-sharing and suggest that, for purposes of clear beneficiary communication and operational simplification, the specialty tier not be included among factors used for tiering exception considerations involving other medications.
        - CMS should consider introducing zero-dollar cost-share tiers, which are designed to promote the use of generics for conditions that are targeted for specialized care management. Such tiers should be excluded from tiering

exceptions or the potentially substantial benefits of this approach would not be realized and both CMS and plans would be exposed to unnecessary expenses that undermine the tier's purpose and effectiveness.

- We also support using the existence of a therapeutic alternative on a lower tier as a criterion for granting a tiering exception request and propose the following definition be used to describe it—i.e. a drug which:
    1. Is FDA approved for the same indication;
    2. Is an appropriate treatment based on current compendia and treatment guidelines;
    3. Has the same therapeutic classification; and
    4. Is delivered via the same route of administration.
- Lastly, we recommend CMS revise Chapter 18 to reflect this guidance and provide updated examples that provide the necessary clarity plans and auditors need to assure compliant implementation and execution.

- **§423.2430 Activities that Improve Healthcare Quality:**
    - (a)(4) – Activity Requirements: CMS proposes to include the costs associated with FWA and Medication Therapy Management (MTM) programs in the numerator of the MLR calculation—essentially removing them from inclusion in the administrative cost spending bucket and instead moving them into the quality improvement category of reporting.

      ESI Recommendation: While we enthusiastically support this proposed change, ESI respectfully requests CMS provide updated, detailed MLR methodology reporting instructions and/or guidance documentation to aid in preparing the simplified reporting data points in line with how it had been compiled for the more detailed reporting template.

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Again, Express Scripts thanks CMS for the opportunity to provide feedback on the proposed rule, CMS-4182-P. As always, we appreciate your consideration of our comments and look forward to continuing to work with you on ways to improve the Medicare program for beneficiaries.

If you have any questions about these comments, please contact me at 202-383-7987 or sasantiviago@express-scripts.com.

Sincerely,

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Express Scripts