



January 16, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically to: <http://www.regulations.gov>

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 (CMS-4182-P)

Dear Administrator Verma:

On behalf of Ascension, I welcome the opportunity to submit comments on the proposed rule entitled, “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.”¹

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As the largest non-profit health system in the U.S. and the world’s largest Catholic health system, Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2017, Ascension provided more than \$1.8 billion in care of persons living in poverty and other community benefit programs. Ascension includes approximately 150,000 associates and 36,000 aligned providers. Ascension’s Healthcare Division operates 2,500 sites of care – including 141 hospitals and more than 30 senior living facilities – in 22 states and the District of Columbia, while its Solutions Division provides a variety of services and solutions including physician practice management, venture capital investing, investment management, biomedical engineering, facilities management, clinical care management, information services, risk management, and contracting through Ascension’s own group purchasing organization.

Ascension is committed to a long-term vision of a sustainable, high-quality health system that serves individuals as whole persons throughout the course of their lifetime. Accordingly, we strongly support the movement towards innovative, value-based care and payment models that support population health. In accordance with this vision and guided by our Mission to deliver compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable, Ascension offers the following recommendations for consideration by the Centers for Medicare & Medicaid Services (CMS).

¹ 82 Fed. Reg. 56336 (November 28, 2017)

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

Ascension strongly supports drug utilization review (DUR) that can successfully identify individuals at risk for opioid abuse and intervene in ways to prevent a downward spiral of abuse, addiction, and possibly even drug poisoning death. There must be a careful balance of the review process and interventions in place to ensure that access to pain medications is not impeded where there is a true medical need for them. As such, while we support the intent of CMS's proposed DUR policy, we are concerned that some of the proposed components could reduce access to pain management for Medicare beneficiaries who are in true need of pain relief. Additionally, we are concerned that the provisions as proposed would increase provider burden without a corresponding level of protection for patients with addiction. These steps may also impede quality good medical care for pain relief. To address these concerns, Ascension offers the following recommendations.

Definition of "Exempted Beneficiary"

CARA specifically provides that certain beneficiaries shall be exempted from being identified as "at risk" individuals for whom a drug management program that includes point of sale edits and lock-in requirements could be applied. Under CARA, exempted individuals are: those who have elected to receive hospice care; those who are residents of certain long-term care facilities; and those individuals that the Secretary elects to treat as exempted individuals. CMS proposes to provide an exemption for individuals diagnosed with cancer and requests feedback on whether additional groups of beneficiaries should be exempted from being identified as "at risk".

Ascension recommends that in addition to finalizing a discrete set of diagnoses or disease states as the bases for exemption, CMS should also consider establishing a process by which a beneficiary or their provider could seek and obtain an exemption; CMS could alternatively clarify that this is intended as part of the case management process. Such a process would allow for an exemption for patients who are not otherwise automatically exempted from a drug management program, but whose providers believe pain management is medically necessary and clinically appropriate.

Ascension appreciates that the CARA statute and the proposed rule would not allow a plan sponsor to limit access to frequently abused drugs until the sponsor verifies with the providers of the beneficiary that the beneficiary is at-risk for prescription drug abuse. To that end, the proposed rule would require that case management be conducted and sets forth proposed parameters and requirements for such case management. We support requiring a plan sponsor to communicate with and obtain prescriber agreement before implementing a pharmacy restriction. We reiterate, however, that CMS should allow providers, as part of this feedback loop, to identify patients who are otherwise not exempt from a drug management program, but should be – without engaging in a burdensome case management process. Further, CMS should clarify what happens when a plan reaches out to multiple prescribers who do not all agree on whether a limitation should be applied. In addition, once a beneficiary is subject to claim edit or lock-in, there should be a process in place to ensure that those facing unexpected or unusual circumstances in which pain medication is legitimately needed do not have necessary pain medication withheld (e.g., if a beneficiary experiences a legitimate emergency and an emergency department physician is not one of the prescribers assigned to a beneficiary who is subject to a lock-in).

Provider Burden and Clinical Guidelines

The burden on prescribing physicians must be carefully considered in CMS's DUR regulations. We have found that when patients are subject to lock-in, the use of a singular prescribing provider may create unintended burdens. For example, such a provider may become overwhelmed with the need to be continuously available to a patient, given that no other providers are able to write certain prescriptions for that beneficiary. We understand that some state Medicaid programs with experience imposing lock-in provisions have found that providers may refuse to serve as a patient's sole prescriber because of the increased burden and complicated care management issues that arise when treating individuals who are likely to be addicted to opioids. Based on these experiences, we encourage CMS to consider incorporating some form of relief for providers who believe that the burden of a DUR is becoming unreasonable or unworkable for their patient(s).

Similarly, we support CMS's decision to use clinical guidelines for a ceiling dose of opioids that conforms with the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline) for plan year 2019. We encourage CMS to continue aligning clinical guidelines with the CDC Guideline in future years, as most prescribers are aware of and generally seek to conform to those guidelines in their own practices. Choosing clinical guidelines that are already widely known and accepted will help reduce burden on providers by creating greater consistency across various coverage programs.

Use of Tax Identification Numbers (TIN) Numbers

CMS proposes to treat providers within a single TIN as one prescriber for purposes of identifying "at risk" beneficiaries who are receiving prescriptions for a large amount of opioids from multiple prescribers or pharmacies. Likewise, a pharmacy that has multiple locations would be collectively treated as one pharmacy under the guidelines. This approach is potentially valuable if a single group practice has multiple providers who are coordinating the care of the patients served by it. However, we are concerned that using a TIN instead of a National Provider Identification (NPI) number could result in providers within the same group prescribing opioids to a patient without knowledge of what other providers within the group/TIN are prescribing. This could arise, for example, in the case of a large multi-specialty group where most physicians act independently of others. We understand CMS's concern with potentially identifying too many beneficiaries as "at risk", but we encourage CMS to weigh this against the possibility of high-risk populations being overlooked under the TIN-based approach.

Plan Flexibility and Monitoring

CMS requests feedback on whether plan sponsors should be allowed to continue implementing independent or different DUR policies. Ascension supports continued authority for plans to apply DUR to other beneficiaries or other drugs that are likely to be abused. Some of these policies could serve to more effectively identify beneficiaries at risk of opioid abuse and serve as models for CMS in the future.

CMS also indicates that it has chosen to define "frequently abused drugs" for the purpose of this policy to include all opioids except buprenorphine for medication-assisted treatment and injectables. CMS will consider revisions to these criteria and would update the list of opioids designated as frequently abused drugs in future guidance. While we appreciate CMS's desire to gain additional experience before potentially designating other controlled substances as

frequently abused drugs, plans that currently monitor for other frequently abused drug products – or that monitor for combinations of drugs – should be allowed to continue this practice.

Finally, CMS indicates that it plans to monitor drug management program compliance with current policy before considering additional flexibilities or changes. We encourage CMS to monitor other features of the program as well. CMS should track whether the program is impeding access to medications for beneficiaries who are at the end of life or who have a true need for opioids to treat a medical condition other than cancer. CMS should also track provider experiences with the program as well as its impact on provider access, particularly in light of some Medicaid programs' experiences. In addition, we encourage CMS to examine the impact of some of the more mature Medicaid lock-in provisions on enrollees' access to providers and provider participation to help guide Part D policy and avoid unintended consequences.

Expanded Medicare Advantage (MA) Plan Flexibilities

Flexibility in the MA Uniformity Requirements and Segmented Benefits Flexibility

Ascension supports CMS's proposed interpretation of the statute and regulations to permit MA organizations (MAOs), beginning in 2019, to: reduce cost sharing for certain covered benefits; offer specific tailored supplemental benefits; and offer lower deductibles for enrollees that meet specific medical criteria, provided that all enrollees who meet the identified criteria are treated the same. We believe the proposed flexibilities would promote greater availability of plan offerings that are better tailored to the needs of various beneficiary segments and would encourage enrollees to seek the most effective coverage for their needs. If this proposal is finalized, however, we encourage CMS to monitor MAOs' proposed plan benefit and cost-sharing designs closely to ensure that the new flexibility does not result in unintended consequences or beneficiary harm. Specifically, as CMS recognizes, flexibility will need to be implemented hand-in-hand with enforcement of the prohibition on discrimination.

Ascension also supports CMS's proposal to allow MA plan benefits to vary by segments. We believe that, like the previous proposal, this initiative would promote more targeted benefit design options for beneficiaries who enroll in MA. Again, CMS would need to ensure that this policy is not used to undermine program non-discrimination requirements.

Cost-Sharing Limits for Medicare Parts A and B Services

CMS proposes to modify existing regulations under which annual cost-sharing limits are established on Parts A and B services so as to prevent discriminatory benefit design. Although we favor providing greater cost-sharing flexibility for MA plans, we also recognize the need to ensure that flexibility does not result in excessive cost-sharing for specific services that may discourage sicker beneficiaries from enrolling in a given plan or result in unexpectedly high cost-sharing amounts for needed Medicare services. Thus, we support the continued use of some service-specific cost-sharing limits. In addition, we favor shifting to the use of MA encounter data as a better measure of actual MA enrollee experience. However, given the current limitations of those data,² we suggest that CMS look at both fee-for-service (FFS) and encounter data to see which would be most appropriate – or use both and use the “greater of” amounts.

² As CMS notes in its Advance Notice proposing changes to the Medicare Advantage risk adjustment program, encounter data for inpatient submissions are low compared to corresponding RAPs inpatient submissions. CMS,

Meaningful Differences in MA Bid Submissions and Bid Review

Ascension appreciates CMS's interest in promoting increased competition and innovation around MA benefit design and services. We share CMS's goal of seeing increased availability of MA plan options that are specifically tailored to different beneficiary populations and move MA plans towards population health. We are concerned, however, that removing the meaningful difference requirements, without also including appropriate safeguards, could allow for the proliferation of plan choices offered by the same MAO in an area that contain only small, indiscernible, or confusing differences. These differences may occur unintentionally or as the result of an MAO seeking favorable risk selection through subtle benefit/cost-sharing and premium designs. Either way, this could ultimately make it more challenging for beneficiaries to make informed plan choices. Thus, if CMS finalizes removal of the meaningful difference requirements, we urge the agency to include appropriate checks on discriminatory plan designs and to closely monitor for gaming. We further recommend that CMS include more detailed information on plan differences on the Medicare Plan Finder and in outreach to beneficiaries.

Coordination of Enrollment and Disenrollment through MA Organizations and Effective Dates of Coverage and Change of Coverage

Ascension supports seamless conversion for dual eligible beneficiaries, as proposed by CMS. We believe seamless conversion into an affiliated MA dual eligible special needs plan (D-SNP) can help expand the availability of integrated care to this targeted group of beneficiaries who might otherwise experience discontinuities and gaps in their care. We also generally support CMS's broader proposal to establish a new "opt in" election process that would be available to all MAOs for the MA enrollments of their commercial, Medicaid, or other non-Medicare plan members. We believe that the proposed change would simplify MA enrollment and promote the growth of the MA program. We recommend, however, that the proposed policies be implemented with sufficient safeguards to ensure that beneficiaries are fully educated about their range of Medicare choices (including FFS and PACE, among others) and the implications of opting-in to an MA plan. We urge CMS to add requirements for commercial plans that also have an MA plan to provide for appropriate notices that explains the opt-in process, other Medicare choices, and the implications associated with each type of Medicare option. We also urge CMS to limit the application of this provision to three years, at which point the agency could assess how it has performed and the effects on enrollment, disenrollment, and plan switching.

Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries

Ascension supports CMS's proposal to allow passive enrollment for full-benefit dually eligible beneficiaries from a non-renewing integrated D-SNP to another comparable plan. We agree that the proposed measure would help to prevent a disruption of services and fragmented care for a population vulnerable to falling through coverage cracks. In response to CMS's request for comment regarding additional beneficiary notices, we believe that an additional notification is not needed. Such notification would likely increase plan burden and could have the unintended effect of creating confusion or even discouraging some beneficiaries from shifting to an integrated D-SNP plan, thus diluting the effectiveness of the policy in promoting the cost-effective, integrated delivery of Medicaid and Medicare services.

Establishing Limitations for the Part D SEP for Dually Eligible Beneficiaries

We support, in concept, CMS's proposal to limit the open-ended monthly Special Election Period (SEP) for dual-eligible and low income subsidy (LIS) beneficiaries because we believe that it would promote greater continuity of care for this often complex patient population. We also recognize, however, that some of these beneficiaries may need to change plans, potentially numerous times, in order to best address their complex healthcare needs. We therefore encourage CMS to consider seriously these competing realities as the agency finalizes any policy around the Part D SEP. In turn, we recommend that CMS adopt one or more of the following accommodations: (1) allow for unlimited SEPs when certain conditions are met, such as a new or altered disease state or diagnosis; and (2) allow dual eligible and LIS beneficiaries or their providers/representatives to solicit CMS for the right to a SEP, based on a change in disease state or life event that might not otherwise qualify for a SEP. In short, we encourage CMS to focus not on the *time* that occurs between changes in enrollment, but relevant changes in the beneficiary's health or life status.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

Background/Solicitation of Comments

CMS seeks comments on whether, in an attempt to encourage plan participation and new market entrants, it should consider implementing a demonstration to test alternative approaches to calculating Star Ratings in such a way as to put new MAOs on a level playing field with renewing plans for a period of time. Ascension believes CMS should undertake such a demonstration because more mature contracts currently can have an unfair advantage, creating a barrier to entry for new and innovative competitors (*i.e.*, contracts offered by a parent organization that has not had another MA contract in the previous 3 years are limited to a 3.5 percent quality bonus payment). To address concerns about masking performance of lower-quality new entrants, CMS could establish a grace period under which a new MAO entrant to a market would enter with a higher star rating, but a withhold or payback methodology would apply if that Star Rating is not achieved within a given period of time (*e.g.*, two or three years). This would allow new entrants to enter a market more competitively, but still hold them accountable to reaching certain quality levels.

In addition, CMS seeks comment on developing and including in the Star Ratings a survey measure of physicians' experiences. Ascension agrees that development of a survey tool for collecting standardized information on physician experiences with health and drug plans and their services would be a positive addition to assessment of plans under the Star Ratings. Including this type of measure would allow for comparison of how well plans interact with physician providers on administrative issues. Problems in these areas can flow through to beneficiaries with respect to specific encounters with providers and also to the extent that physician participation in some plans suffers due to poor plan interactions with providers.

Contract Ratings

CMS seeks comment on whether to calculate Star Ratings at the plan level, in lieu of current policy that calculates such ratings at the contract level. Ascension supports calculating Star Ratings at the plan level, where feasible. This information would be more useful to beneficiaries – who choose among plans, not contracts. Plan-level Star Ratings would also prevent MAOs from structuring plans within contracts for purposes of attaining higher quality bonus payments.

Contract Consolidations

Ascension supports CMS's proposal to modify how the Star Ratings are assigned when an MAO consolidates contracts of similar type. The proposed approach would discourage MAOs from consolidating contracts for purposes of masking poor performance to increase quality bonus payments. In our view, this weighted enrollment methodology should also be used when consolidations occur as contracts are bought and sold between different parent organizations. We believe it is unlikely that a lesser quality contract would improve immediately when purchased by a different MAO and combined with a higher quality contract, given the time it takes for process changes to be implemented and to result in measurable quality improvement.

Adding, Updating, and Removing Measures

While we recognize it might slow down the expansion of Star Ratings measures, Ascension supports the proposed approach for adding new measures through notice and comment rulemaking, with feedback initially solicited on potential new measures through the Call Letter process. This proposed process would allow for maximized stakeholder input on possible new measures. In addition, we support the proposal to place new measures on the display page for at least two years prior to including them as Star Ratings measures. This would permit plans, CMS, and stakeholders to gain experience with measures, including assessing their reliability and validity, to better discern whether measures are appropriate for calculating Star Ratings.

Data Integrity

CMS proposes to modify its policy for adjusting Star Ratings when a contract's appeal measure data are found to be inaccurate, incomplete, or biased. Ascension agrees with the proposal to permit scaled reductions of 1 to 4 stars to account for the degree to which independent review data are missing. In our view, this approach is fairer than the current one-size-fits-all assignment of 1 star regardless of the extent of data incompleteness.

Measure-Level Star Ratings

Ascension agrees that it is appropriate for CMS to consider alternatives to the current methodology for determining the Star Rating cut points, with the goal of making the scores needed to achieve specific Star Ratings less volatile from year to year. When investigating these alternatives, CMS may want to consider addressing concerns about "cliff" situations in which contracts with nearly identical scores have different Star Ratings. One approach could be to assign a contract that falls just short of a category cutoff with a "+" or "-" designation to its Star Rating.

Categorical Adjustment Index

Ascension is committed to serving all persons, with special attention to those who are poor and vulnerable. In our experience, there is undoubtedly increased burden associated with caring for plan members with lower socioeconomic status. Not only do these members generally need additional healthcare services, they often require greater effort and resources to activate – e.g., getting in touch with them, helping them focus on and navigate health issues, and even providing information and transportation necessary to use services. Additional costs can also include coordinating care across a wide array of providers and facilities not otherwise accessed by their peers and providing appropriate levels and modes of customer service. These enhanced services are essential to meeting the needs of these beneficiaries and should be fully

supported. We applaud CMS for its ongoing work in this space and strongly support continued efforts to account for these costs so that plans and providers can continue serving these beneficiaries in ways that best meet their needs.

Changes to the Days' Supply Required for the Part D Transition Process

Ascension supports CMS's proposal to conform the transition supply provided in the long term care setting (currently 90 days) to that provided in the outpatient setting (currently 30 days) so that the transition supply in both settings is the same number of days. We agree that this measure would be helpful in reducing the waste of prescriptions. CMS also proposes to change the current 30-day transition supply requirement to a one-month supply (*i.e.*, to change the transition supply provided in the long term care setting and outpatient setting to a one-month supply). We similarly support this proposal.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

Ascension supports CMS's proposal to permit Part D sponsors to immediately remove or change the preferred or tiered cost sharing of brand name drugs immediately and substitute or add therapeutically equivalent generic drugs, provided specified requirements are met. We favor the proposed changes to expedite generic substitutions because they should promote increased use of generics and result in savings for beneficiaries, Part D plan sponsors, and the Medicare program, while at the same time facilitating appropriate beneficiary notice. One caveat to our support for the proposed policy, however, is with respect to permitting plans to implement expedited generic substitution drugs that have a very narrow therapeutic range. For certain drugs, such as digoxin and warfarin, replacement medications may cause medical harm. We thus recommend that CMS adopt the proposed policy but take into account that, for some drug classes or categories, exceptions may still need to apply to the immediate substitution policy.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost-Sharing

We appreciate CMS's efforts to improve incentives for Part D enrollees to choose lower cost follow-on biological products over more expensive reference biologicals. Although only about six of these products are available today, more are in the pipeline and could, if appropriately used, help to slow the rising cost of Part D specialty drugs. CMS proposes to treat follow-on biological products as generics in expressly defined situations, by revising the regulatory definition of a generic drug to include such products – but only in the case of enrollee cost sharing once the enrollee is in the catastrophic phase of the Part D benefit. We support this proposal.

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

We support the proposed policy but note that we would not support eliminating the meaningful difference requirement as it applies to basic and enhanced Part D plans. We are concerned that doing so could lead to the same issues as described above in the context of MA.

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

We appreciate CMS's consideration of potential policy approaches to reduce beneficiary cost-sharing for high cost medications, such as applying prescription drug manufacturer rebates to

the price of a Part D drug at the point of sale. Instead of pursuing the policy CMS has outlined, however, we believe the agency should – with opportunity for stakeholder input – pursue policies that reduce unit costs of Part D drugs. Doing so will not only reduce patient costs at the point of sale, but will serve to drive down premiums and overall federal healthcare program spending.

Reducing the Burden of the Compliance Program Training Requirements

We support CMS’s proposal to eliminate a federal training requirement for certain downstream providers and entities that have relationships with MA and Part D plans. Many MAOs already have programs in place for downstream providers so the elimination of the federal training requirement should not have any impact on the compliance capabilities and will eliminate unnecessary and duplicative provider and plan burden.

Medicare Advantage Plan Minimum Enrollment Waiver

CMS proposes to eliminate the requirement that a minimum enrollment waiver be renewed at years two and three, opting instead to informally track the enrollment in the second and third years of the waiver. Ascension supports simplifying the process by dropping the second and third year waiver renewal process and notes the importance of such waivers as a way to encourage plan sponsors to enter the MA/PD markets, enabling smaller organizations to enter with a manageable scale and to scale up over time.

Revisions to Regulations Governing Communication/Marketing Materials and Activities

Ascension supports CMS’s proposal to define a smaller group of materials and activities as “marketing” materials and activities and to continue providing oversight and review of those materials and activities. Historically, the lack of specificity about which materials are considered to be marketing materials has resulted in CMS review being overly broad with too many documents needing review. We support CMS’s focus on those materials that present the greatest risk of misleading or confusing beneficiaries while eliminating the review of non-controversial materials that have not intended to influence enrollment.

Preclusion List – Part D Provisions

Section 507 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires pharmacy claims for covered Part D drugs to include a valid prescriber NPI. Under regulations, Part D sponsors (or their pharmacy benefit managers) must reject pharmacy claims that lack the NPI of the provider who prescribed the drug. We encourage the agency to enforce the statutory requirement as effectively and efficiently as possible, taking into account the burdens that may be imposed on plans and providers, as well as on beneficiary access to needed medications. For example, we caution that the proposed enforcement mechanism could prove problematic with respect to certain providers in limited contexts – such as teaching hospitals with residents and interns who may use the NPI of their attending physician. As such, we encourage CMS to provide additional clarity around how the final policy will be implemented to account for these and similar situations that may arise, in order to maintain beneficiary access.

Prescriber Preclusion List

Ascension supports the elimination of the prescriber enrollment requirement. There is concern among physicians and other prescribers in the community that enrollment has not reached an

appropriate level to ensure access to medicines by Medicare beneficiaries. The preclusion list approach focuses attention and resources on those prescribers that act in ways that are detrimental to patients as well as to the Medicare program. We support the beneficiary protection policies that CMS proposes and encourage the agency to ensure that information on the new policy (if finalized) is provided to beneficiaries in advance to minimize confusion and disruption. CMS should carefully align the policies it finalizes with respect to the implementation of CARA in the context of the proposed prescriber preclusion list. This should include policies to ensure that enrollees with medical needs for pain medication will have appropriate access to that medication should a physician or other prescriber that prescribed pain medications for that enrollee be placed on the preclusion list. We also encourage CMS to ensure that this proposal, if finalized, is implemented in an administratively feasible manner, such that it is easily incorporated into prescription claims systems.

Preclusion List – Part C/Medicare Advantage Cost Plan and PACE Provisions

CMS proposes to substitute a preclusion list policy for individuals and entities under MA, in lieu of requiring these individuals and entities to enroll as Medicare providers or suppliers. Under the proposed policy, plans would be prohibited from paying claims from providers (including prescribers) on the preclusion list who furnish items and services to their enrollees. This policy would also apply to PACE organizations.

Our comments focus on the application of the proposed policies to PACE organizations. Ascension believes the proposed substitution of a preclusion list policy for the current provider enrollment policy addresses a number of concerns that PACE programs have previously expressed about those enrollment requirements. However, given the unique nature of PACE as a provider type that is substantively different from an MAO, we raise the following operational issues for CMS's consideration. We would also request that CMS delay the effective date of any finalized policy with respect to PACE organizations for one full year after the effective date of the final rule to afford PACE organizations sufficient time to adapt to and implement the new requirements.

We interpret the proposed requirement on PACE organizations with respect to the preclusion list (as well as with respect to the exclusion list maintained the Office of Inspector General (OIG) of the Department of Health and Human Services) to apply to the staff of the PACE organization (whether employed directly by or under contract with the organization) as well as with respect to entities with which a PACE organization may contract to furnish care, such as inpatient hospitals, nursing homes, and post-acute care settings. However, we do not interpret the proposal to require the PACE organization to verify whether employees or contracted staff of a hospital or other provider of services entity with which the PACE organization contracts are included on the preclusion list. We would ask that CMS clarify this point if it finalizes the proposal.

Because the criteria for inclusion on the preclusion list focuses on enrollment (specifically whether a provider or supplier is under a re-enrollment bar or would have been under a re-enrollment bar were they enrolled as a Medicare provider or supplier), the preclusion list policy is focused on the types of providers of services and suppliers that *could* enroll as Medicare providers/suppliers. Thus we interpret the proposal to be inapplicable to the type of staff members of the PACE interdisciplinary team who are not eligible for Medicare provider or supplier enrollment, such as nurses, recreational therapists, and drivers. We encourage CMS to confirm that these categories of PACE staff individuals are not subject to inclusion on the

preclusion list. PACE organizations will continue to adhere to relevant state and federal law for pre-employment background checks and similar beneficiary protection requirements.

Removal of Quality Improvement Projects (QIPs) for Medicare Advantage Organizations

Ascension supports the proposal to eliminate QIPs as a requirement on MAOs. We believe Chronic Care Improvement Programs (CCIPs) are more effective and efficient means of addressing and measuring quality of care in managing chronic conditions of plan enrollees. Eliminating QIPs would permit MAOs to focus more attention and resources on CCIPs, which have demonstrated positive impacts on enrollee health. Additionally, onerous bureaucratic requirements that duplicate existing reporting requirements pose unnecessary and costly burdens on plans and providers; some information reported for purposes of QIPs duplicates information reported for the MA Quality Star Ratings program. It appears from the tenor of CMS's statements in the preamble to the proposed rule that while the agency has received an enormous amount of data, much of that data exceeds its needs or the agency's capacity to use them meaningfully. For all of these reasons, we support the proposal to eliminate QIPs and the associated burden on plans and providers.

Reducing the Burden of the Medicare Part C and Part D MLR Requirements for Fraud Reduction Activities

CMS makes a number of proposals with respect to the calculation of the MLR of a MA plan, a MA-PD plan, or Part D plan. As previously noted, Ascension supports efforts to eliminate data reporting requirements that are excessive, duplicative, or that do not serve any useful purpose. However, CMS's proposal to only require reporting of the MLR percentage and amount of any remittance owed to CMS for each contract runs the risk of reducing transparency and access to useful data. The public availability of MLR data reported by plans to the agency fosters meaningful analysis of plan performance; it also permits new entrants to a Medicare Advantage market to develop an understanding of the overall performance of plans in that marketplace, which in turn fosters greater competition and innovation in the market. We would encourage the agency not to finalize this proposal and to foster transparency by making MLR data reported by MA plans publicly available.

Ascension supports the proposed clarification that a Medication Therapy Management program offered by a Part D plan sponsor or a MA-PD plan is a quality improvement activity that may be counted in the MLR numerator by the plan. The agency should monitor whether the clarification has the intended effect of increasing the number of qualified enrollees in these programs. While we support efforts to improve fraud, waste, and abuse efforts, we encourage CMS to fully consider the potential impact of including all activities that could be characterized as or related to fraud reduction in the MLR numerator, as this could create new burdens on providers under the guise of fraud reduction. MA and Part D plans are currently incentivized to engage in robust fraud reduction activities and applying a uniform set of rules for calculating the MLR between the commercial market and the Medicare program is a reasonable and efficient policy. There is also the concern that because the proposal will result in a shift of a plan's administrative costs to the cost of paying benefits under the plan, this could create another hurdle for value-based performance and payment programs to overcome. We strongly believe that CMS should facilitate, wherever possible, the implementation of value-based performance and payment programs.

Physician Incentive Plans – Update Stop-Loss Protection Requirements

With respect to physician incentive plans, CMS proposes to update stop-loss deductible limits; to codify the stop-loss methodology for future updates; to permit the use of actuarially equivalent arrangements to protect against significant financial loss for risks associated with serving particular groups of patients; and to allow non-risk patient equivalents to be included when determining the deductible. Ascension generally supports CMS's proposed approach and believes that the policies will provide flexibility as well as a greater ability to address the risk of substantial loss under physician incentive plans.

Conclusion

Ascension thanks you for the opportunity to comment on these issues. If you have any questions, please contact Mark Hayes, Senior Vice President for Federal Policy and Advocacy at 202-898-4683 or mark.hayes@ascension.org.

Sincerely,

A handwritten signature in blue ink that reads "Rev. Dennis H. Holtschneider" followed by a horizontal line.

Reverend Dennis H. Holtschneider, C.M.
Executive Vice President and Chief Operations Officer
Ascension