



June 6, 2011

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Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW Room 445-G
Washington, DC 20201

RE: CMS–1345-P; Proposed Rule Regarding Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

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

Dear Dr. Berwick:

AHIP appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS') proposed rule that would implement Section 3022 of the Patient Protection and Affordable Care Act (ACA) which contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP). We applaud the agency's goals to reduce fragmentation of care delivery and better align incentives to encourage the provision of better, safer and more cost-effective health care services. At the same time, we believe that care must be taken to build on — not turn back — progress that is being made in the private sector to achieve these objectives. Otherwise, CMS runs the risk of testing old methods that have already been explored and discarded by the private sector, and reduces its chances of meeting its goals as quickly as possible.

Over the past several years, health plans have partnered with hospitals and physicians to promote accountable care models that are transforming the delivery system by offering better care at lower cost. Plans have played critical roles in such initiatives by providing tools and data to support population based care, providing programs and staff to better coordinate care, and structure provider contracts to reward high quality performance and reductions in cost.

This experience is the prism through which we offer comments that the proposed rule should be changed to better align with the promising results observed in the private sector.

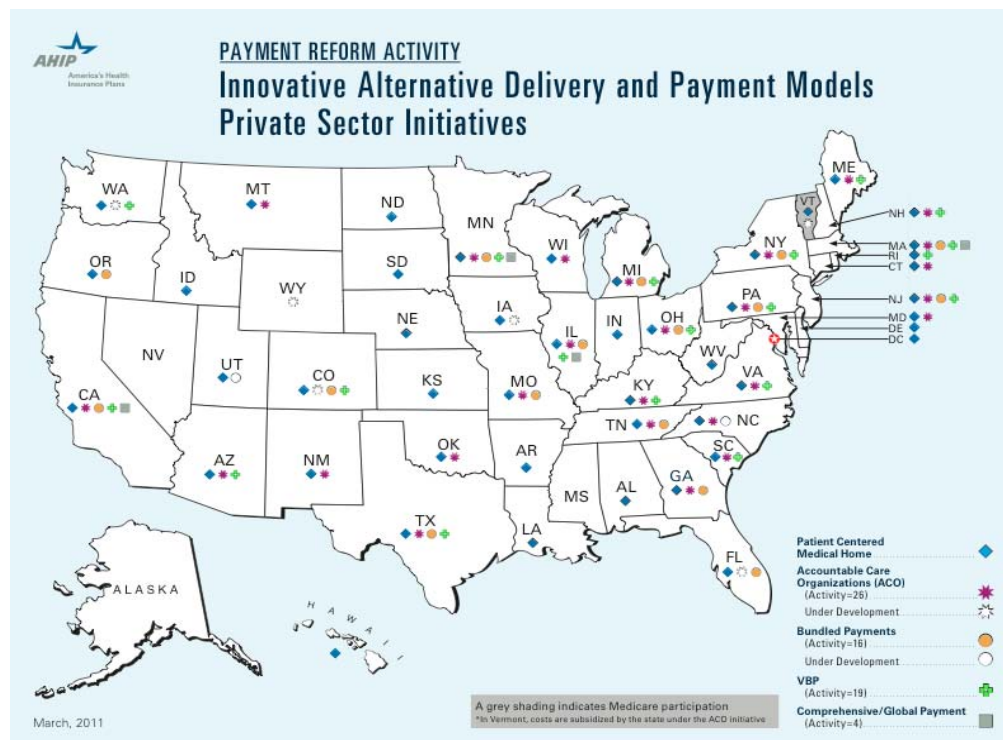
A. SUMMARY OF RECOMMENDATIONS

Our key recommendations are in five areas:

- The MSSP should learn from, and build on, private sector accountable care models.
- ACOs should be encouraged to utilize the tools, infrastructure, and experience health plans can provide to help transform the delivery system.
- The MSSP should transition away from the outdated fee-for-service system to one that rewards value, quality, and better health outcomes.
- The agencies should establish a regulatory framework that promotes choice and competition and avoids increasing provider consolidation and cost-shifting that would lead to higher costs for consumers.
- Other recommendations to improve the MSSP.

B. The MSSP Should Learn From, and Build On, Private Sector Accountable Care Models

Health plan-provider partnerships in the private sector have been exploring, testing, and implementing accountable care models and alternate payment systems for several years. The map below illustrates a snapshot of such activity which is currently underway and growing rapidly.



We urge CMS to acknowledge the important role that health plans are playing in driving change and think more broadly about the role that plans can play in partnering with CMS to achieve its objectives.

Without public and private sector alignment, particularly in the areas of quality metrics, how a patient is assigned to an ACO, and provider and patient incentives, the MSSP could turn back the clock on the important strides that already have been achieved in the commercial market. For example, under the proposed rule, ACOs would successfully meet quality standards in the first program year by merely reporting on quality measures, rather than achieving specific quality targets. In contrast, models in the private sector typically require entities to demonstrate improvement by setting quality targets for a core set of measures, which an entity must meet to share in savings for the initial year.

While the Pioneer ACO Model begins to recognize the efforts of the private sector in promoting accountable care, CMS misses an opportunity under both the MSSP and the Pioneer ACO Model to fully capitalize on the progress being made in the private sector by developing program requirements that do not align with existing efforts and could create marketplace disruption.

C. ACOs Should be Encouraged to Utilize the Tools, Infrastructure, and Experience Health Plans can Provide to Help Transform the Delivery System

The construction of the proposed regulation is too narrow and is at odds with the way successful ACO models are working in the delivery system today.

1. The critical tools needed to transform the delivery system

Over the past several years, health plans have partnered with providers to develop and participate in alternative payment systems that are transforming the delivery system by offering better care at lower cost. These partnerships offer multiple dimensions of health plan support, including:

- **Population health management** – Availability of timely data to identify patients at risk, and opportunities to improve the health outcomes of individuals who routinely access the health care system as well as those who do not;
- **Disease and case management** – Case managers and other personnel to help coordinate and navigate care for patients with specific acute or chronic conditions across multiple providers and settings;
- **Treatment decision support** – Sophisticated IT infrastructures to provide real-time access of key data at the point of care and condition-specific care guidelines;
- **Consumer self-management tools** – Resources and tools to help consumers better manage their own care and adhere to treatment plans and wellness programs designed to their specific conditions;

- **Data supporting provider performance improvement** – Ability to measure, collect, aggregate and analyze information across care and on provider performance, supporting efforts to pinpoint gaps in care and help drive quality improvement;
- **Establishment of quality provider networks** – Identification of qualified providers periodically assessed to ensure credentials remain current make them a valued partner in developing and managing provider networks for ACOs;
- **Sharing data on patient encounters** – Access to data on care delivered outside the ACO helps providers better monitor patients, and compare performance within and across providers and geographic regions;
- **Managing insurance risk** – Predictive modeling tools to help assess and manage risk, while the numerous reserve and solvency requirements help create a stable financial infrastructure for plan-provider ACO partnerships;
- **Detecting fraud and abuse** – Use of cutting-edge data analytic techniques and multi-disciplinary special investigations units to identify and address practices leading to substandard care; and
- **Value-based benefit design** – Evolving benefit designs promote utilization of evidence-based health care services and offer patient incentives for making the appropriate choices.

These health plan tools and infrastructures will become even more important as the delivery system continues to shift from fee-for-service (FFS) to care models that better align incentives across providers and beneficiaries. Health plans are operating these programs today and their involvement in developing new models helps address and alleviate regulatory, legal and other challenges that arise relating to risk sharing, distribution of savings, and other program elements.

2. Important lessons from the past

Lessons learned from past experience with similar groups of clinicians and facilities, provider-sponsored organizations (PSOs) and physician-hospital organizations (PHOs) during the 1990's also illustrate the importance of the health plan role. PSOs and PHOs had entered into commercial arrangements to take on varying degrees of financial risk for managing the health care of a defined population. These arrangements did not result in the highly anticipated improvements in quality and efficiency, and in fact led to the closure or bankruptcy of 147 physician organizations serving 4.1 million patients in California between 1998 and 2002. The experience resulted in confusion, discontinuity of care and market disruption for consumers.

This experience reinforces the value of health plans in assisting provider organizations to successfully manage risk and perform other important operational functions. In fact, a recent report by the Integrated Healthcare Association – which analyzed

California's experiences with physician organizations over the last 30 years – included as a key lesson learned that health plans should play an integral part in fostering ACO development.¹

3. The importance of revising provisions in the proposed rule that would restrict participation

The proposed rule limits the role that health plans and other non-provider stakeholders can play in the formation and governance of ACOs. For example, providers must have at least 75 percent control of an ACO's governing body. We question the practicality of CMS prescribing such an arbitrary governance standard. CMS' focus should be ensuring that an ACO has a demonstrated ability to treat individuals, improve population health, and create programs and perform outreach to reduce unnecessary care. To that end, ACOs should have the maximum amount of flexibility to create governing bodies that best meet their individual needs and help them achieve the intended goals of the MSSP, and should not be subject to a "one-size-fits-all" approach to governance which would prohibit the establishment of potentially effective alternatives.

Setting a 75 percent threshold may discourage the development of the types of partnerships that will be necessary to achieve the objective of encouraging the development of a high performance healthcare system. Two circumstances are immediately problematic. First, providers that are unable to take financial risk on their own may not apply. Second, consumers make up a majority of the governing body of some health plan-owned provider groups. These existing provider groups should be permitted to use their existing governance structure.

Finally, the proposed rule does not speak to the ability of ACOs to delegate various functions through contracting with entities, such as health plans, IT vendors, etc. Examples of types of functions that could be delegated include collection and compilation of quality data, IT infrastructure and electronic data exchange, and case management. In order to assure that the MSSP is successful and brings in small provider groups and newly established entities, CMS should explicitly acknowledge that ACOs have flexibility to delegate certain functions. Specifically, it should be clarified that there is no limitation on the delegation of non-clinical functions to non-provider entities.

Given the important role that health plans can play in supporting ACOs to meet their quality and cost goals, we urge CMS to reconsider the unintended consequences of establishing an arbitrary control threshold requirement, explicitly acknowledge that ACOs have flexibility to delegate functions to third party entities such as health plans, and include new provisions that encourage health plans to bring their knowledge and capacity to the challenges of building a high performing system.

¹ James C. Robinson and Emma L. Dolan, "Accountable Care Organizations in California: Lessons for the National Debate on Delivery System Reform," Integrated Healthcare Association White Paper, 2010.

D. The MSSP Should Transition Away from the Outdated Fee-for-Service System to One That Rewards Value, Quality, and Better Health Outcomes

As noted by numerous third parties, the current Medicare payment system provides few disincentives for overuse, underuse or misuse of care, and does not reward efficiency. Despite these findings, the proposed rule would require ACOs to use one of two payment models based on FFS payment. By selecting such models, CMS is developing a program that offers far fewer incentives to deliver value-based care than models in the private sector, which are implementing alternative payment mechanisms and other incentives, including partial capitation, bundled payments, episode case rates, and global payment models.

Both Congress and CMS recognize the potential opportunity to better align incentives that seek to link payment to quality outcomes under the MSSP. The MSSP's statutory language allows the Secretary to use other payment models, including partial capitation models, for making payments under the MSSP. Additionally, CMS, in the proposed rule as well as in the CMMI Pioneer ACO Model announcement, highlights the fact that real change in care delivery cannot occur when the reimbursement methodology remains based on FFS and there is little consideration of aligning incentives across providers and beneficiaries. While we strongly support the testing of innovative payment and service delivery models, we are concerned that there is a missed opportunity for leveraging existing provider-payor partnerships to drive accountability across the entire Medicare population.

E. The Agencies Should Establish a Regulatory Framework that Promotes Choice and Competition and Avoids Increasing Provider Consolidation and Cost-shifting that Would Lead to Higher Costs for Consumers

We have considered the potential implications of the proposed rule in light of the related documents that were simultaneously released by other federal agencies, including the Federal Trade Commission (FTC) and the Department of Justice (DOJ) *Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (Antitrust Policy Statement) and the *Notice on Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center* (Waiver Notice) released by CMS and HHS Office of the Inspector General (OIG). We believe that all agencies should work together to develop a set of rules that will establish an appropriate regulatory framework which serves to protect, and not create additional risks for, consumers. Thus, we urge the federal agencies to consider the following key issues and recommendations.

1. To help address consumer needs and promote choice, certain accountable care models should not be advantaged to the detriment of others.

Given that providers have different levels of readiness, CMS should recognize the potential value of a variety of accountable care models and structures. For example, while many stakeholders have recognized the ability of hospitals and integrated health care systems to form ACOs, structures that involve different types of providers – such as physician group practices or IPAs that include physicians of a single specialty (e.g.,

primary care) or multiple specialties – have demonstrated their ability to meet the intended goals of the MSSP.

In certain parts of the country, physician groups already have an ability to meet capitalization and IT infrastructure requirements, and provide its patient population with timely access to care. Moreover, other physician groups that may have lower levels of readiness could form partnerships with health plans to help ease transitions and perform ongoing functions related to the operations of the ACO. To help promote patient-centered care and emphasize the foundational importance of effective primary and specialty care, we urge CMS to think more broadly about the proposed rules to allow the types of partnerships that are developing in the private sector delivery system (among health plans, physicians and hospitals) to be brought to the Medicare program. This would expand the types of organizations able to participate.

2. If ACOs perform health plan functions, they should be subject to the same requirements that health plans meet.

ACOs that assume risk for losses and/or perform other health plan functions which are regulated at the state level (e.g., subject to state financial and consumer protection standards) should have to meet the same standards required of health plans. These standards include financial requirements (e.g., capital, reserve and solvency requirements); network requirements (e.g., ensuring access to adequate numbers and types of providers); filing, reporting and disclosure requirements; and quality improvement requirements, including accreditation standards and other consumer protection standards. If ACOs are not subject to the same standards, consumers receiving care from an ACO may have less access to care, receive care of lesser quality, be faced with increased costs, and/or be more vulnerable to discontinuation of coverage if unforeseen events occur, such as a flu pandemic or similar disaster impacting the health care system.

While licensure and regulation of ACOs, to a large extent, will depend on applicable state law, CMS could build on the language in the Regulatory Impact Analysis of the proposed rule which states that “the agency does not believe there is anything in the proposed rule that either explicitly or implicitly pre-empts any State law, and that the proposed rule will not have a substantial direct effect on State or local governments, preempt State law, or otherwise have a Federalism implication”. We urge CMS to consider final rule language that makes clear its intentions that these regulations are not expected to impede states from carrying out their regulatory responsibilities to establish similar licensing, solvency and exchange standards for entities performing similar functions.

3. The antitrust agencies should modify their proposed antitrust policy statement to minimize the potential risk of increased prices due to provider consolidation.

There is a concern that increased provider consolidation that may result from the formation of more ACOs will increase costs to payers, employers, consumers, and others. Thus, we applaud the Antitrust Agencies, as well as CMS, for recognizing that successful efforts to move the health care delivery system into one that delivers, higher

quality, more efficient care, must rely upon competition and the role of existing antitrust law in protecting competition.

- **Summary of our comments on the Antitrust Policy Statement**

We believe that the FTC and DOJ, in creating a screening process, appropriately create a framework that attempts to balance the goals of providing sufficient guidance and an efficient process to entities seeking to participate in the MSSP, while ensuring that there is sufficient review of entities that could potentially harm consumers from the aggregation or inappropriate exercise of market power. This framework, however, should be modified in the following seven areas to further minimize the risk of harm to consumers:

- The thresholds utilized in the Antitrust Policy Statement for safety zone treatment and mandatory review should be lowered to address the risks of an under-inclusive screening process, and to take into account the exclusivity of primary care providers in ACO arrangements consistent with past antitrust guidance;
 - The Antitrust Policy Statement should be made more complete in its application by including newly-formed ACOs that would not be reviewed under the current Statement (e.g., ACOs formed by merger, but not subject to Hart-Scott-Rodino reporting) and to more clearly provide for review of changes to ACOs that occur after they are in the MSSP;
 - The Antitrust Policy Statement should indicate explicitly that when an MSSP participant is a member of a provider system, primary service area (PSA) calculations should reflect the share of the provider system in the PSA, rather than the share of the individual provider;
 - The Antitrust Policy Statement should give MSSP applicants the option of moving directly to the review contemplated by the mandatory review process, rather than first using the PSA-based screening process;
 - The Antitrust Policy Statement should give MSSP participants wishing to demonstrate their desire to avoid market harm a fuller chance to evidence their intentions by adding to and clarifying the list of conduct to avoid;
 - The Antitrust Policy Statement should provide for the antitrust agencies to obtain aggregated information to test whether there is potential cost-shifting from Medicare to commercial patients; and
 - The Antitrust Policy Statement should build in a process of evaluation and review to allow for improvement of the analysis, as well as the data utilized, over time.
- **All MSSP applicants should be subject to renewed Antitrust Policy Statement analysis and potential antitrust review based on any changes to their composition during the MSSP**

MSSP participants are prohibited from adding ACO “participants” during their three year agreement to participate in the MSSP, but the MSSP participants are allowed to remove *or add* ACO “providers/suppliers.” In a number of possible situations, the application of this rule could raise antitrust concerns, essentially allowing a MSSP participant to add, either at once or over time, physicians, hospitals, or others to a degree that creates market power and undermines the review process. CMS’s proposed rule related to the MSSP contemplates re-review by the Antitrust Agencies in some circumstances, but the re-review also appears to be limited to certain situations. In addition to the current language related to the re-review process, MSSP participants should be required to notify CMS and the Antitrust Agencies of any changes — whether through contract, acquisition, employment, or otherwise — that would materially increase their primary service area shares, including but not limited to, changes to physicians, other health care professionals, hospitals, other facilities, and physician groups.

For more details on the above recommendations, please see AHIP’s letter to the FTC and DOJ in response to their *Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*.

4. The proposed fraud and abuse waiver for the distribution of shared savings under the MSSP should remain tailored, while adding practical safeguards, and care should be taken to ensure that the federal fraud and abuse laws do not impede the continued advancement of health plan and provider collaborations in the private market.

The federal fraud and abuse laws addressed in the Waiver Notice include Stark, Anti-kickback, and Civil Monetary Penalties. These laws historically address two harms: (1) overutilization incentives in a fee-for-service system; and (2) underutilization risks in a Prospective Payment System (PPS) or episodic reimbursement payment system.

The shared savings component of the ACO reimbursement presents both overutilization and underutilization risks. At its core, the MSSP remains centered on FFS payments, and these payments are significantly greater in volume than any potential shared savings. The waiver proposal is authorized under the ACA recognizing the possibility that existing federal fraud and abuse laws do not fit neatly given some of the features of the ACO models proposed under the MSSP or from the Innovation Center.

We have three key recommendations regarding the proposed Waiver Notice:

- The waiver related to the ACO’s distribution of shared savings to participants should not be made on a blanket basis. Rather, the waiver should be subject to clear and achievable conditions and safeguards to assure that these distributions promote the goals of an accountable health system and are monitored to guard against beneficiary harm. Balance can be achieved in the creation of practical waiver conditions, with the goal of maintaining flexibility with respect to the distribution of shared savings, but at the same time protect against practices that

result in inappropriate underutilization of services, cost-shifting, steerage, “swapping” or other harms to consumers with private coverage. CMS/OIG have long flagged these practices for concern in the context of federal health care programs.

- The waiver process should not be expanded beyond the distribution of shared savings (consistent with the current Waiver Notice) so as not to implicate overutilization incentives or other improper practices.
- Ensure that the federal fraud and abuse laws do not impede the continued advancement of health plan and provider collaborations in the private market. To the extent that there are provider or other stakeholder concerns about whether private sector based accountable care arrangements implicate the federal fraud and abuse laws because of indirect relationships between these private sector arrangements and the Medicare MSSP or other public programs, CMS/OIG should consider issuing additional guidance to make clear that the financial relationships in the private sector arrangements are too attenuated to implicate the federal fraud and abuse law because of the role that health plans play in the distribution of any shared savings.

That said, if because of the unique or special nature of the MSSP or CMMI programs, CMS/OIG believes these laws could be implicated, it should propose a simple waiver with respect to the distribution of shared savings or similar payments from private payers, consistent with the solicitation of comments in the Waiver Notice. In all cases, the goal of CMS/OIG should be to ensure that the federal fraud and abuse laws do not impede the continued advancement of health plan and provider collaborations in the private sector designed to achieve accountable care. In addition, we also raise the following comment related to the Waiver Notice’s question regarding section 1115A programs conducted by the Innovation Center:

- The additional flexibility provided in the Pioneer Program or other CMMI programs, while beneficial, may unintentionally provide further encouragement to engage in activities or create referral patterns that may encourage or steer particular Medicare beneficiaries into one of these ACO arrangements. Consistent with our comments on the proposed MSSP waiver, such efforts or arrangements should not inadvertently be protected through a blanket waiver.

We elaborate on these recommendations in AHIP’s separate letter to CMS and OIG on the Waiver Notice.

5. The federal agencies should recognize and seek to address the potential risks of cost-shifting between public programs and the private sector.

A crucial area that the proposed rule does not address is the potential risk of cost-shifting between the Medicare program and the private sector. ACOs could have an incentive, and through the aggregation of market power an enhanced ability, to obtain shared savings payments by reducing Medicare expenditures to achieve “savings” under the MSSP and compensate for the reduced expenditures by charging higher rates

and possibly reducing quality of care in the private market. This is not the intent of ACA or the MSSP. Thus, the MSSP should require reporting by ACOs to determine whether such cost shifting is occurring, and any MSSP participants that engage in cost shifting should be terminated from the MSSP, or at a minimum, have their shared savings payments reduced by the amount of the cost shift.

If cost shifting is not measured and discouraged, then system-wide health care costs could increase resulting in an overall increase in federal spending and higher costs for employers and individuals. Moreover, with costs being shifted (as opposed to the achievement of true savings related to delivery system transformation), the purpose behind the MSSP, in evaluating the effectiveness of the model proposed, will not be achieved.² We recommend that the proposed rule be modified to reflect that CMS, as well as the FTC and DOJ has an important role in detecting and discouraging cost-shifting by MSSP participants. Specifically, the proposed rule should:

- Not allow participants to obtain shared savings payments by reducing Medicare costs and compensating for this reduction by exercising market power in the commercial market. The MSSP, and CMS's rules directly governing the MSSP, should allow it to gather aggregate information from ACOs to determine whether such cost shifting is occurring and terminate the participation of MSSP Participants that are engaging in cost shifting, and
- As CMS is gathering cost, quality and utilization data from ACOs to test whether the MSSP's eligibility criteria furthers MSSP goals, it should share with the Antitrust Agencies aggregated cost and utilization information from ACOs related to possible cost-shifting by MSSP participants. This aggregated information should include for each MSSP participant: total Medicare costs for assigned beneficiaries and total costs for all populations receiving care in the ACO.

6. Aligning MSSP requirements with the requirements of other public programs will help ensure better access to care and promote choice for consumers.

We urge CMS to strive to align MSSP and the Pioneer Accountable Care Model requirements with the requirements of other public programs. Inconsistencies could result in the unintended consequence of disrupting patient access to care, such as in Medicaid. Because of past experience with shared risk and outcomes-based contracts in other public and private sector initiatives, provider groups likely will be able to achieve financial gains in the MSSP. Given the potential for financial gains in the MSSP alongside underpayments in Medicaid, providers may decide to participate in the MSSP rather than continuing their participation in Medicaid. The movement of

² There is precedent for CMS to consider whether savings are truly being generated through reform of the delivery system and greater accountability in care as opposed to shifting costs to other payers or limiting care to Medicare beneficiaries. We offer, as an example, the analysis of gain sharing arrangements by the OIG under the advisory opinion process. The civil monetary penalties provision prohibits inducements for reductions or limitations of direct patient care services provided under a Federal health care program. OIG Advisory Opinion No. 08-21. The Secretary's authority to design the shared savings regulations so as to ensure that cost savings are genuine is unassailable under her general authority to enact regulations to implement the statute.

providers away from Medicaid would impact the availability of adequate numbers of primary care providers (PCPs) for other populations and may create access problems for underserved populations that rely on Medicaid.

Similar challenges may arise for Medicare Advantage (MA). If providers participating in both the MSSP and MA find the MSSP to be more financially attractive and/or less burdensome in terms of government quality and reporting requirements, they may encourage their patients to move from the MA program to the MSSP. The combination of more financial gain and less burdensome requirements, as well as the rule that PCPs be exclusive to one ACO in the MSSP could unfairly disadvantage the MA program and the beneficiaries served by it.

We urge CMS to vigilantly monitor the MSSP for potential steerage of both providers and patients, and put in place safeguards to ensure that long-term viability of MA, Medicaid, and other public programs. Finally, the proposed rule does not reference dual eligibles and the potential impact of the MSSP on the broader integrated care models that CMS is proposing. We urge CMS to address these issues in the final rule, while taking account of the concerns expressed above.

F. Other Recommendations to Improve the MSSP

We support the goals of reducing fragmentation of care delivery and aligning incentives to encourage better care and better health at a lower cost. In this section, we provide a range of specific technical recommendations to further these goals.

1. Eligibility and Governance

The minimum number of assigned beneficiaries for an ACO to be eligible to participate in the MSSP should be increased. According to the proposed rule, CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants is 5,000 or more. An ACO with only 5,000 beneficiaries may not produce a large enough sample size for certain measures to ensure that performance assessments are reliable. Thus, CMS should consider increasing the minimum number of beneficiaries for which an ACO may be held accountable.

It should be clarified that ACOs have flexibility in how shared savings are distributed to allow for appropriate incentives for ACO participants. While the proposed rule requires transparency on how an ACO uses the shared savings for beneficiary programs, ACO infrastructure or shared payments to providers who are part of the ACO, the rule does not speak to how an ACO should distribute the shared savings among ACO participants and partners. In the final rule, CMS should make clear that an ACO has the flexibility to distribute savings in variety ways (e.g., distribution of shared savings could be based on levels of capitalization contributions) to best allow the ACO to meet the intended goals of the MSSP.

2. Assignment/Attribution

Under the proposed rule, beneficiaries will be assigned to an ACO if they receive a plurality of their primary care, as measured by accumulated charges, from primary care physicians within that ACO. In some cases, the plurality standard may result in assignment of a beneficiary to an ACO when that beneficiary lacks strong ties to the ACO. Therefore, beneficiaries should only be assigned to an ACO if a minimum threshold requirement is met, as well as the plurality standard. For example, a “snow bird” (i.e., an individual who resides in different locations during winter months), may receive a significant amount of his/her care outside of an ACO.

We urge the agency to consider and balance two issues: setting a threshold too high, which may reduce the number of eligible beneficiaries participating in the ACO (making it more difficult for ACOs to meet eligibility requirements); and setting a threshold too low, which could require a participating provider to be responsible for a beneficiary’s care when the beneficiary has received most of his/her care outside of the ACO.

CMS should pursue its options for expanding the definition of an ACO primary care provider upon which assignment is based to include nurse practitioners (NPs) and physician assistants (PAs). The statute requires that patients be assigned to ACOs based on receipt of primary care services from a PCP. The current definition of primary care provider (PCP) is limited to physicians. Thus, patients may not be assigned to ACOs if they see nurse practitioners (NPs) or physician assistants (PAs), who frequently function as PCPs by providing primary care services for certain beneficiaries, particularly in rural areas. We do not believe that the drafters of the statute intended to exclude NPs and PAs from the definition, particularly given that the Institute of Medicine and others have called for a greater reliance on such practitioners. Thus, we recommend that a technical change be sought to allow for expanding the definition of an ACO PCP to include NPs and PAs.

3. Data Sharing

HIPAA Protection

To promote consistent protections for consumers, HHS should ensure that ACOs regulated under the proposed rule and the Pioneer Programs are “covered entities” under HIPAA and the HITECH Act and are expected to comply with the corresponding regulatory requirements. The final regulations should clarify the applicability of the federal Health Insurance Portability and Accountability Act (HIPAA) statute and regulations, including the recent HITECH requirements, to entities that fall under these regulatory requirements, to ACOs. Since the HIPAA privacy and security requirements protect consumers from improper uses and disclosures of their protected health information, HHS should ensure that the strong HIPAA privacy and security protections remain intact for the benefit of individual consumers.

The final regulations should retain the proposed provision in § 425.5 which requires ACOs to have compliance programs. To support various types of ACOs, we encourage HHS to retain the flexibility for organizations to develop their own compliance plans based on their size, resources, and unique business environments

operating under generally-accepted industry guidelines. As the preamble explains, an ACO's compliance plan will be required to address how the organization will comply with applicable legal requirements, although the specific design and structure of an effective compliance plan may vary depending on its size and business structure.

Attribution

Under the proposed framework of retrospective attribution, ACOs may receive limited identifiable data on a prospective basis relative to their historically assigned beneficiary populations. This information is provided for the purposes of conducting population-based activities relating to improving health or reducing health care costs, protocol development, case management, and care coordination. Assuming the retrospective assignment methodology is retained in the final rule, other data elements, including patients' last four diagnoses codes, information about hospitalizations including discharge diagnoses codes, prior providers seen in the last three years, and information about the last three emergency room visits, including dates of service and the facilities visited, should be added to the proposed list in § 425.19(c)(1).

Performance Assessment

Under the proposed rule, an ACO may request on a monthly basis a limited set of beneficiary-identifiable data for purposes of evaluating provider performance, conducting quality assessment and improvement activities, and performing population-based health functions. Beneficiaries, however, would be given the opportunity to opt-out of having their claims data shared with the ACO, potentially leaving the ACO without the information necessary to deliver the appropriate care to the population for which they are accountable. To best promote patient engagement and ensure the development of targeted programs to improve the health of their populations, ACOs should receive as much information upfront as possible on its assigned beneficiaries. We believe that more public dialog and evaluation of the care management and patient choice issues should occur before an opt-out approach is adopted.

Data Use Agreements

Finally, requiring data use agreements is not the best approach for facilitating the release of certain identifiable data. The HIPAA Privacy Rule sets specific requirements for covered entities' use of data use agreements (DUAs) for the limited purposes of research, public health, or health care operations. However, the rationale discussed in the preamble is unclear about when and how DUAs would be used in the context of ACOs and align with existing HIPAA requirements. For example, one alternative could be to specifically recognize that data use agreements are not required for permissible disclosures under HIPAA. Another option could recognize the ACO program as a joint program administered by the Medicare program and ACOs, both functioning as HIPAA covered entities (subject to our comments and recommendations listed above).³

³ See, 65 Fed. Reg. 82477 (stating that where a public agency is required or authorized by law to administer a health plan jointly with another entity, each would be a covered entity with respect to the health plan functions it performs)

Additional Technical Recommendations

Two technical fixes pertaining to data sharing should be made to the final regulations. With respect to technical issues, There is a discrepancy in the data elements listed in §425.19(c) and the elements included in the corresponding preamble language. The regulation indicates that beneficiary names, date of birth, and HICN (health insurance claim number) will be included. However, the preamble indicates on page 19556 that sex would also be included. A technical fix is needed so that the data elements listed in the preamble are the same as those listed in the regulations. In addition, the proposed rule uses the terms “aggregated” and “de-identified” interchangeably. Technical fixes are needed to clarify CMS’ intent, and recognize the difference between these two terms.

4. Quality Metrics and Performance Standards

Aligning Incentives with Performance

Under the proposed rule, ACOs would be required to implement 65 quality measures starting in the first year. Implementing such an extensive set of metrics in the first year may not be feasible for inexperienced ACOs, particularly given that the benchmarks for these measures are not yet available.

To best ensure that the goals of the MSSP are met, CMS should require ACOs to implement quality metrics through a phased approach in which ACOs agree, at the start of the program term, to implement a smaller core set of metrics in the first year of the MSSP, with the remaining measures being added in later years. Given our recommendation that a smaller core set of measures be used, we believe that ACOs should only be eligible to receive shared savings in the first year if they meet quality performance targets on this core set. This approach would better promote accountability by creating sufficient incentives for more experienced ACOs and providers that have already demonstrated their abilities to both report and meet benchmarks in the private sector.

The core set of measures for the first performance year should: (a) be meaningful; (b) have the potential to significantly improve patient outcomes; (c) consist of clinically enriched administrative measures that are already being reported in private and public sectors; and (d) be consistent with measures used in other public programs such as the Medicare Advantage Star Program, the Hospital Value-Based Purchasing Program and the Inpatient Prospective Payment System as well as other ACA programs.

Strengthening Impact

Measures included in this core set should be meaningful (i.e., demonstrate proficiency) and have the potential to significantly improve patient outcomes. To the greatest extent possible, CMS should use outcomes, rather than process, measures. We

recommend, for example, that CMS eliminate from its measure set the Coronary Artery Disease Beta Blocker Therapy measure (#55 on the proposed measure list) given that this is a process measure that already has a high level of attainment among clinicians. We also recommend the initial use of clinically enriched administrative measures with preference given to HEDIS measures where appropriate. This recommendation will promote consistency across various public and private sector programs, given that Medicare Advantage and the commercial market have historically utilized HEDIS measures, and reduce reporting burdens for providers.

We also believe that some measures will be more impactful if they are combined to form composite measures (e.g., the three Chronic Obstructive Pulmonary Disease measures could be combined into one measure). Composite measures help assess the full spectrum of care a patient receives for a clinical condition delivered across care settings. The proposed measure set includes composite measures for certain conditions such as diabetes and CMS should consider expanding the use of composites for evaluating the care delivered to patients by an ACO. Regardless of the final measure set selected, CMS should be explicit about how the measures will be assessed and make available specifications for the measures as soon as possible.

Under the proposed rule, ACOs participating in the program will be required to comply with changes made to the program during the course of the agreement, such as modification of the quality measures used to determine eligibility for shared savings. To reduce uncertainty of new measures being added in future rulemaking, measures should be added in future years of the program only if they meet the needs of the ACO's patient population. Measures should be removed throughout the program term if they are later found to be unreliable, unactionable, or do not meet the needs of the population being served. Such an approach will provide ACOs with incentives to improve performance, and at the same time, ease transitions for more inexperienced ACOs by setting realistic goals.

Setting the Bar to Achieve Results

The minimum attainment level used to measure ACO performance should be set at a level higher than is currently being considered by CMS. CMS should consider adopting the minimum attainment levels that are used in other public programs, such as the Hospital Value-Based Purchasing initiative. After Year 1 of the program, performance standards will be based on a measures scale with a minimum attainment level and a performance benchmark for each measure. According to the preamble of the proposed rule, CMS is considering setting the minimum attainment level at 30 percent or the 30th percentile of the Medicare FFS or MA rate. To best promote quality improvement, we urge CMS to set the minimum attainment level higher than the 30 percent or 30th percentile of the Medicare FFS or MA rate. CMS should consider adopting the minimum attainment levels that are used in other public programs, such as the Hospital VBP initiative, which uses the median as the minimum attainment threshold.

Under the proposed rule, ACOs would be required to report performance using the Group Practice Reporting Option (GPRO) data collection tool. In light of the reported

problems with this tool in the Physician Quality Reporting System program, there should be another standardized option available in addition to the GPRO tool.

Under the proposed rule, at least 50 percent of an ACO's primary care providers must be "meaningful electronic health record (EHR) users" by the start of the second performance year in order to continue to participate in the MSSP. Given that the use of EHR technology should be promoted throughout the delivery system, we believe this requirement also should be extended to hospitals. In addition, both primary care providers and hospitals (whether or not they participate in the meaningful use incentive program) should be required to demonstrate administrative efficiencies as part of the MSSP requirements (e.g., verifying insurance eligibility electronically, submitting electronic claims, etc.). Fostering the use of electronic processes will help to reduce administrative costs, reduce the number of denied claims due to ineligible members and provide greater transparency for patients regarding their insurance eligibility and benefits prior to care delivery.

Measures should be more evenly distributed across the five domains. The 65 measures included in the proposed rule fall within 5 equally weighted domains. The number of measures within each domain is as follows:

- Patient/caregiver experience (7 measures)
- Care coordination (16 measures)
- Patient safety (2 measures)
- Preventive health (9 measures)
- At-risk population/frail elderly health (31 measures)

These measures/domains will be used to establish the quality performance standards that ACOs must meet for shared savings. Once performance is scored on each measure, the scores will be grouped into respective domain scores. Each domain score will be aggregated and weighted equally to arrive at a single score that will be used to determine a quality sharing rate for which the ACO is eligible. We urge CMS to consider adopting a more even distribution of measures across the domains. For example, as there are only two measures in the patient safety domain, those measures will have a greater impact on an ACO's overall score than a measure in the at-risk population domain, which includes 31 measures. In the alternative, CMS could consider differential weighting, similar to the Hospital Value-Based Purchasing, for the domains. The Hospital Value-Based Purchasing program weights the clinical process of care measures domain at 70 percent and the patient experience of care domain at 30 percent.

5. Expenditure Benchmark

A hybrid adjustment factor should be used to adjust the initial benchmark for growth that is a combination of both national and local growth in Medicare FFS Parts A and B

expenditures, with a gradual phase-out of the national growth rate component. In establishing the initial expenditure benchmark, expenditure data will be trended forward to the most recent year using a national growth rate, rather than establishing a flat dollar amount or using State or local growth rates. Local growth rates will more accurately reflect cost trends in the ACO's geographic area. If CMS determines that a national rate should initially be used for updating the benchmarks, we recommend that a hybrid adjustment factor be used that includes both national growth and local growth, and gradually trends toward Medicare FFS growth at the local level.

6. Shared Savings/Shared Risk Models

The proposed two-track approach which offers ACOs the option of a shared risk model under Track 2 or a transition to a shared risk model under Track 1 should be retained in the final rule. While a shared savings only track may be appropriate for newly formed organizations to gain experience with accountable care models, a model that includes shared risk is necessary to drive meaningful change. Transitioning ACOs under the one-sided model to a shared savings and risk model in the third year and offering more mature ACOs the option to enter into a shared savings and risk model in the first year recognizes the importance of shared risk in the delivery transformation necessary to achieve the three part aim.

Modifications to the shared savings calculation should be made to encourage participation of ACOs, particularly those ACOs that are already high performers. Specifically, CMS should consider: (a) a reduction or elimination of the MSR under the 2-sided model; and (b) an increase in the Quality Sharing Rate under the 2-sided model for ACOs that are identified as high performers. An ACO's average per capita Medicare expenditures for the performance year must be below the benchmark by at least a Minimum Savings Rate (MSR) to account for normal expenditure variation. Under the two-sided model, the MSR is 2 percent. CMS should consider eliminating the MSR or reducing the MSR to 1 percent under the two-sided model for certain ACOs that have demonstrated that they are high performers. Under the two-sided model, an ACO can receive a shared savings payment based on quality performance of up to 60 percent. The maximum rate is based on a perfect quality score. CMS should also consider increasing the percentage under the two-sided model to 70 percent or 75 percent for high performing ACOs. Reducing or eliminating the MSR, in tandem with increasing the Quality Sharing Rate under the 2-sided model will make participation in the MSSP more attractive to high performing ACOs that have experience with risk contracts.

7. Public Reporting and Transparency

In addition to the proposed reporting requirements, ACOs should be required to provide information on total cost of care as well as information at the individual provider level. Under the proposed rule, CMS proposes to make certain information regarding ACOs publicly available in a standardized format. This information would include:

- Quality performance standard scores;

- The amount of any shared savings performance payment received by the ACOs or shared losses owed to CMS; and
- The total proportion of shared savings that was distributed among ACO participants and total proportion that was used to support quality performance, better care for individuals, better health for populations, and lower growth in expenditures.

While transparency of this type of information is important, additional information should be reported to help promote accountability and allow consumers and other stakeholders to make more informed health care decisions. Specifically, ACOs should be required to report:

- Medicare total costs for beneficiaries assigned to the ACO and total costs for all populations receiving care in the ACO, as well as the percentage of the ACO's patients who are participating in the MSSP. This information may help determine whether an ACO is meeting Medicare FFS savings targets by merely increasing prices in the commercial market (i.e., cost-shifting); and
- Individual provider performance information on quality, cost and patient experience. Benchmarks should be set and a set of performance measures that may include physician-level HEDIS measures and patient experience/Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures should be used to allow for meaningful comparisons of providers. As ACOs report provider performance information, they should do so in accordance with the Consumer-Purchaser Disclosure Project's *Patient Charter for Physician Performance Measurement, Reporting and Tiering Programs* aimed at promoting consistency, efficiency and fairness of reporting and make physician performance information more accessible and easier for consumers to understand.

ACOs that already report quality information at the local level due to participation in a local exchange should be deemed to have met the public reporting requirement with respect to their quality performance scores. Deemed compliance for reporting quality performance scores to a local exchange will help alleviate some of the burdens associated with reporting this information. Additionally, promotion of reporting at the local level is consistent with the goal of enabling consumers to have comparable information on providers within their markets.

CMS should make available benchmark information on providers who are not participating in an ACO but are providing care to Medicare beneficiaries. CMS should also provide aggregated information relating to how ACOs are spending their shared savings payments. Benchmark information on providers not affiliated with an ACO will enable consumers and others to compare ACO and non-ACO provider performance. Additionally, while ACOs are required to report individually on how their shared savings payment are being used, similar information on an aggregate basis will enable broader evaluations about the characteristics and impact of the overall MSSP.

8. Evaluating Beneficiary Participation

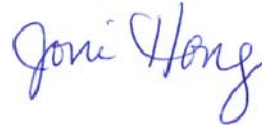
CMS proposes to monitor ACOs for avoidance of at-risk beneficiaries. We support CMS' proposal that these monitoring activities include use of beneficiary surveys and medical records review. We recommend that beneficiary surveys include surveys of those beneficiaries who leave an ACO will help inform CMS regarding beneficiary experience at the point of care and within the ACO.

We strongly urge CMS to consider the exciting innovations in care delivery and payment reform that are occurring in the private sector, the central role that health plans are playing in these changes and the opportunity for the agency to build on this experience to more quickly achieve results for the Medicare program as a whole.

Sincerely,



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Executive Vice President, Clinical Affairs &
Strategic Planning



Joni Hong
Senior Counsel