



February 6, 2015

Marilyn B. Tavenner Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–1461–P Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Proposed Rule

Dear Administrator Tavenner:

The American Academy of Home Care Medicine (Academy) appreciates the opportunity to provide our comments regarding the Centers for Medicare and Medicaid Services (CMS) Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Proposed Rule.

The Academy represents those physicians and non-physician providers who are caring for some of Medicare’s sickest, isolated and most costly beneficiaries—those with multiple chronic conditions who are home-limited due to illness and disability. As a result, the Academy and its members are uniquely positioned to work with the CMS on policy and practice transformation to meet the triple aim for the high risk-high cost population, as well as, the increasing numbers of rising risk and rising cost beneficiaries. To improve the Medicare Shared Savings Program (SSP) as well as the care of these Medicare beneficiaries, the Academy provides the comments in this letter that are summarized below. The Academy supports CMS:

1. Provisions to modify definitions, to increase data elements provided to ACOs, to increase claims data availability and to improve the attribution methodology. We also recommend expansion of your proposals in certain areas;
2. Provisions regarding Track 1 and 2 modifications, we offer a proposal for Track 3 considerations as well as proposed elements for the Alternative Performance Based Risk Option; and,
3. Provisions regarding waivers of the 3 day rule for SNF, post acute referrals, homebound definition, and offers comments for your consideration regarding Telehealth and a recommendation to develop Part B coverage and broader payment for home infusion.

Details of these comments are discussed below.

1. Provisions to modify definitions, to increase data elements provided to ACOs, to increase claims data availability and those that improve the attribution methodology.

Provision of Aggregate Data Reports and Limited Identifiable Data

CMS proposes and requested comments on increasing the amount of data available to ACOs for all prospectively assigned beneficiaries and for Tracks 1 and 2 beneficiaries assigned based on plurality of services. We support the proposal to add specific data elements to that which are made available to the ACOs as described below.

- Demographic data such as enrollment status – this is important to focus the activities of the ACO and its participants and as there is enrollment movement in the marketplace relative to Medicare Advantage health plans, duals health plans, etc. This will eliminate a great amount of wasted resource within the ACOs.
- Health status information such as risk profile, and chronic condition subgroup – This is important to add so that ACOs can conduct population based activities relating to improved health, add practice capability for high risk high cost beneficiaries. For example, to add the availability of housecall providers and the ability to redesign their practices. This in turn will contribute to enhanced care coordination and quality assessment and improvement activities.
- Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including dates and place of service – This is critically important to add for the contribution to risk based population health management initiatives such data will provide; The targeting of interventions to avoid hospitalization and enhanced ability to design approaches to manage and track ACO beneficiaries. Additionally, this will support analysis of the quality and path of post acute provider care of ACO beneficiaries leading in time to increased quality and cost effectiveness.
- Expenditure information related to utilization of services – this is critically important to receive so that ACOs can target their population health management activities and internally track performance.

Again, we fully support, based on Academy member experience with SSPs the proposal to provide these data elements in the circumstances described for Track1, 2 and 3 ACOs and each under the HIPAA protections as set out and understood.

Claims Data Sharing and Beneficiary Opt-Out

We fully support your provisions in this area as reflected below.

Amending § 425.704 to reflect a proposal to share beneficiary identifiable claims data with ACOs participating under Tracks 1 and 2 that request claims data on beneficiaries that are included on their preliminary prospective assigned beneficiary list or that have received a primary care service from an ACO participant upon whom assignment is based during the most recent 12-month period, at the start of the ACO's agreement period, provided all other requirements for claims data sharing under the Shared Savings Program and HIPAA regulations are met. Also to share beneficiary identifiable claims data with ACOs participating under Track 3 that request beneficiary identifiable claims data on beneficiaries that are included on their prospectively assigned beneficiary list.

Revise § 425.312(a) and § 425.708 to reflect policy that ACO participants use CMS approved template language to notify beneficiaries regarding participation in an ACO and the opportunity to decline claims data sharing.

Modify § 425.708 to reflect the streamlined process by which beneficiaries may decline claims data sharing and to add a new paragraph (c) to § 425.708 to reflect the proposal to honor any beneficiary request to decline claims data sharing that is received under § 425.708 until such time as the beneficiary may reverse his or her claims data sharing preference to allow data sharing as this is not always the case.

We agree with the assessment that the proposed revisions would reduce beneficiary confusion about the Shared Savings Program and the role an ACO plays in assisting the beneficiary's health care provider(s) in improving their health and health care experience, while still retaining a beneficiary's meaningful opportunity to decline claims data sharing.

We agree that it is appropriate for activities that have contributed to confusion to be moved from the ACO to CMS and as you note for sharing preferences directly through CMS, an agency with which beneficiaries have an existing relationship.

We also agree that the proposals will streamline ACO operations and provide for improved performance based on more timely receipt of claims data. We agree that the requirements that remain and will continue with ACOs will meet the desired communication and transparency needs. Additionally, while not explicitly discussed, the requirement to be a covered entity or to have a business associate agreement in place to receive the data of beneficiaries who receive service outside of the ACO, while initially requiring ACO resource; will in turn lead to increased levels of communication, and coordination of care across communities. In time, this will benefit beneficiaries and the Medicare program.

Assignment of Medicare FFS Beneficiaries

The Academy supports each of the elements proposed below that a Medicare beneficiary would need to meet to be eligible for assignment, if the beneficiary, during the 12-month period used for assignment;

- Has at least 1 month of Part A and Part B enrollment and does not have any months of Part A only or Part B only enrollment.
- Does not have any months of Medicare group (private) health plan enrollment;
- Is not assigned to any other Medicare shared savings initiative. Moreover, we recommend the CMS, should apply this same rationale that the beneficiary assignment should govern SSP reconciliation and not the TIN of a participating provider. In this manner, beneficiaries and Medicare will receive the aggregate benefit of providers participating in multiple SSP initiatives, and yet each month of attribution to a specific SSP initiative will be only be reconciled for shared savings consideration for the months they were in a specific SSP and their will be no double counting at the TIN or NPI level;
- Lives in the U.S. or U.S. territories and possessions as determined based on the most recent available data in the beneficiary records regarding the beneficiary's residence at the end of the assignment window.

We also recommend that dual eligible programs be dissuaded from auto-assigning beneficiaries who already participate in ACO or other SSP models. The Academy is learning from ACOs and from IAHP participants that the opportunity to increase the numbers of beneficiaries in their programs is challenged based on the assignment policies of duals programs and the growth of Medicare Advantage plans. Thus, to be able to participate as a SSP in a meaningful way, CMS assistance is requested to be able to maintain an ongoing relationship with assigned SSP beneficiaries.

Definition of Primary Care Services

The CMS seeks comment on proposals to expand the definition of primary care services to include the TCM services represented by CPT codes 99495 and 99496 and the new chronic care management (CCM) code (now established by CMS as CPT 99490), and to make any future revisions to the definition of primary care service codes through the annual PFS rulemaking process.

The Academy supports these provisions and we believe they will support beneficiaries and the Medicare program. CPTs 99495, 99496 and 99490 each require that a primary care relationship be established by the provider and be recognized by the beneficiary. Additionally, only one primary care provider is able to be paid for one of these services in a month and thus this further supports the primary care relationship. This will also enhance future care coordination and the goals of SSP as many beneficiaries receiving TCM and CCM do so as a result of hospitalization (required for TCM) and often return to the community without an identified primary care provider. This provision will support the interest of those establishing the relationship for the purpose of these services to become the ongoing PCP of these beneficiaries and this in turn will support improvement in care and reduced cost. The Academy also supports the provision to add new primary care services in the PFS rulemaking as this will contribute to flexibility and to the improvement of care and reduced cost as CMS discusses in the proposal.

Consideration of Physician Specialties and Non-Physician Practitioners in the Assignment Process

CMS seeks comment on a proposal to include NPPs in Step One provided that a physician provided primary care service was rendered. The Academy agrees with this provision for the reasons set out and moreover recommends that the provision be strengthened to include these NPPs based on primary care services they render within the TIN and in collaborating relationship with a physician within the ACO. This will increase access to care and make more efficient use of the stretched primary care workforce. Additionally, as noted the proposal will align the ACO attribution process more closely with that which CMS has established for PQRS and for the VBPM.

Additionally, CMS requests comment on how to define that the service of the NPPs is primary care for attribution purposes. CMS may want to consider additional or sub-classification. This would be a level beyond the "NPP" such that the NPPs seeking Step One inclusion and their ACOs (would attest through the CMS system), that they are primary care providers. Another means is for CMS to evaluate the place of service codes and to initially extend Step One participation to those NPPs who are rendering services in ambulatory/non facility places of service.

We strongly support the proposals in this area and would add our recommendation with the belief born out of the Academy experience that this will increase the number of beneficiaries with access to ACO care and will again lead to improvements in care and reduced cost by supporting the relationship of NPPs with physicians. As you note, this will increase recognition and support the provision of team based care that is producing a growing evidence base for the positive results of such care.

2. Provisions regarding Track 1 and 2 modifications, proposal for Track 3 considerations as well as proposed elements for Alternative Performance Based Risk Option

The Academy appreciates the CMS recognition of the value of home care medicine in general and specifically the role that the results of IAH are serving to inform CMS proposals for ACOs and payment

policy. We want to take this opportunity to contribute a few observations as you note the value that housecalls may serve in contributing to ACO performance in improving care and lowering cost.

One overarching point is that home care medicine rendered to a targeted high risk high cost population has been shown to improve care and reduce costs. As a result, we recommend that the benefits of home care medicine for the high risk, high cost beneficiaries be included in all CMS payment models, including, but, not limited to ACOs.

To support that end, the Academy has submitted a Transforming Clinical Practice Initiative SAN application to help promote the practice transformation that is required to accept risk and produce triple aim results. Also to that end, there are principals that CMS will want to incorporate as it uses the information from the success of home care medicine in Veterans Affairs, in managed care organizations, and that from IAH demonstration practices.

The principles that should be included are:

- Patient population targeting;
- A payment methodology that
 - is accurate in detailing and projecting the risk of this population utilizing population appropriate frailty factors and other methodology components
 - that covers the cost of care for this population
 - that creates a payment incentive to provide care to this population as it is much easier and less expensive from a practice development perspective simply to not take on this high risk population.

We have made presentations to CMS officials on the specifics of these principles and would be pleased to present this information to other CMS staff as well.

We next turn to comments on proposals regarding Track One, Two and Three including beneficiary assignment, attestation and benchmarking.

Track One Proposals

We support the CMS proposal to permit ACOs to continue participating under a one- sided participation agreement after their first 3-year agreement. The CMS and provider community have learned of the tremendous investment and transformation required to operate as a successful ACO. In fact, there has been variable performance across ACOs even under the one side model. ACOs have decided to discontinue participation and other provider organizations are also reluctant to participate as ACOs knowing they would have to take on the potential of loss just as the processes and systems for success were becoming embedded across the ACO providers. As a result, the opportunity to have another 3-year agreement, in addition to the other proposed improvements in this Proposed Rule, will provide encouragement to participate as an ACO.

The proposal to participate for another 3-year term is also timely as the DHHS announced intention to move CMS from fee for service to payment based on quality and value. This proposal along with the Transforming Clinical Practice Initiative (TCPI) will support the goals of the Medicare Program to move to quality and outcomes based payment. The Academy also supports the proposal to have ACOs that were terminated less than half of the way through the period to re-enter for the reasons noted above. However, we do not support the proposal to reduce the amount of shared savings in a second 3 year period. CMS should provide as broad based encouragement for participation as possible. Provider

organizations and their subparts that would generate savings, yet require financial support, should not have to make a choice between losing the opportunity to share in savings at the same level as the initial agreement vs. taking on risk before they are fully prepared. Again, this will support the national systemic change that CMS seeks for Medicare and to also encourage for private payment models.

Track Two Proposals

We support CMS proposal to increase shared savings opportunity and limit losses under your proposed Track 2 modification. The increase in shared savings opportunity and limit to losses will along with the other provisions in this Proposed Rule encourage ACOs to stay in the program and participate under Track 2. At the same time, we believe that it is important to include the waiver provisions that CMS has proposed for Track 3 to all of the ACO Tracks. The flexibility and benefits that the waivers will provide of improved care (decisions) and cost savings should be available to all ACOs and to all beneficiaries regardless of the ACO to which they are assigned. Additionally, once experience is obtained from the waivers in the MSSP, CMS should seek legislation so that the improved practice and cost savings that result from the waivers are available across the Medicare program where similar triple aim incentives are in place. . The “lessons learned” from the waivers in the MSSP should also become available in a real time basis to the provider community through the CMS collaborative role in the TCPI.

However, we do not support the proposal for variable MSR based on size of an ACO population. The Academy has experience with Part B providers that are small, urban based as well as those located in rural areas. It is seen from CMS data and published analysis that these smaller providers are able to produce savings – savings that exceed even the proposed MSRs based on population. As an example, the beneficiary threshold for IAH practices is 200 eligible enrollees. As a result of this successful performance by small shared savings programs, and as there are not enough of these programs around the country to meet the need wherever it exists and how remote the location, the CMS should do all that it can including through the MSR to encourage participation. As noted in our recommendations for an Alternative Performance Based Risk Option below, an approach the CMS could consider would be to use (its) multiple years of ACO experience to establish a MSR that controls for the potential of chance over years of ACO participation and establish this for the ACO track. This would incorporate the successful experience of small ACOs and thus recognize that size of an ACO can also mean that small ACOs can be the most successful (and this is the opposite, again, born out of results, of the variable MSR approach).

The Academy SAN application in relation to PTN with remote providers was developed in part to increase the number of home care medicine practices in all areas of the country. Therefore, we recommend that CMS not adopt the graduated MSR as this would discourage the formation of ACOs in the remote areas of need. This would be counterproductive to the goals of this Proposed Rule, the MSSP, and the recent announcement of transition of Medicare to a program that pays based on quality and value.

Track 3 Proposals

Beneficiary Assignment and Attestation – The Academy recommends based on practice experience in IAH and also in ACOs that CMS strengthen the opportunities for voluntary beneficiary attestation. We recommend strengthening the role of attestation when prospective assignment would occur on its own or through hybrid approach. This recommendation is made for the same reasons discussed relating to benchmarking and with regard to high risk high cost beneficiaries. Using CMS language in the proposed rule there is a higher amount of “churn” among the high risk population (that would benefit from

housecalls) as compared to less high risk beneficiaries. The concern with prospective assignment by itself is that there is not opportunity to manage high risk beneficiaries for a long enough period to improve care and lower cost. Rather, the period of high cost would be that associated with the ACO and this would discourage growth of programs such as housecalls that meet the needs of the high risk high cost beneficiary population.

Therefore, the Academy supports CMS strengthening of attestation opportunities such as you tested for the Pioneer ACOs. This is also similar to the voluntary agreement of IAH beneficiaries to be included as IAH enrollees in the IAH Demonstration. Additionally, for the reasons discussed in the Proposed Rule, this attestation in a hybrid approach would encourage ACOs 1) to manage all of their beneficiaries as if they would be included in the ACO, and, would, 2) provide an ACO a reasonable opportunity to establish an ongoing relationship and management of high risk high cost beneficiaries; with the confidence supported by attestation that they will have the time to improve beneficiary care and reduce cost.

Attestation would also serve to reduce the circumstances where a beneficiary would elect to receive care outside of the ACO. Moreover, given the concept that beneficiary awareness and engagement in the SSPs is desired to help achieve the triple aim, the CMS should consider provision where beneficiary attestation supersedes plurality in a hybrid approach. This recommendation is based on (our IAH) experience that an ACO may take over the care of a beneficiary due to change in medical status and the beneficiaries prior care may not have been associated with the ACO. We also see an attestation model being applied through the Medicare Fee Schedule and the requirements in the chronic care management (CCM) and transition care management codes that a beneficiary have an agreed upon (and in the case of CCM – signed agreement to document), primary care relationship with a provider. This truly serves to engage the care going forward from the perspective of both the beneficiary and the provider. Similarly, attestation could be used and this would recognize an important primary care relationship will exist despite the lack of prior (plurality) services.

Benchmarks

As a general observation, the Academy recommends moving low cost ACOs to regional benchmarks over shorter periods of time and conversely moving ACOs in high cost areas to regional benchmarks in a longer period of time. This recommendation is to provide the ACO the opportunity to adjust.

This is also based on the evidence from various Medicare programs and demonstrations that with specific regard to high risk, high cost beneficiaries that the cost of this patient population is similar across the country even though the cost of care for the average Medicare beneficiary may vary greatly around the country. As a result, there should be accommodation provided for the benchmarking particularly of high risk beneficiaries that reflects this cost heterogeneity regardless of area of the country.

Incorporating the finding of high cost beneficiary heterogeneity in benchmarking will encourage ACOs to arrange for the care of the high risk population and will encourage these ACOs to develop housecall practices or relationships with housecall practices that have shown to improve care and reduce cost. This will increase the opportunity for CMS to achieve cost savings for the most expensive beneficiaries across the greatest range of ACOs regardless of track and regardless of location.

For this same reason, the Academy adds the general recommendation that CMS maintain recognition of cost against the non ACO, regional, fee for service population / that established through county cost profile. This is so ACOs will have the opportunity to reflect success that would not be as possible where an ACO is compared increasingly to its own prior performance.

Alternative Performance-Based Risk Options

Based on its experience with ACOs through the VA, and Independence at Home, the CMS should consider development of an alternative performance and risk adjusted option with a frailty adjuster for the medically complex that do not meet all of the clinical criteria for IAH and, yet, remain high risk and high cost. This option would reflect some of the regulatory elements and lessons learned of both ACOs and IAH, in particular it would add the discipline that Track 2 now has through enforced risk, but without the discouragement that having actual dollars at risk creates. Instead it would use the “opportunity cost” of potential shared savings as the penalty for poor performance, as in IAH, by excluding ACOs that do not meet their MSR for 2-3 consecutive years.

These elements are as follows:

- a. Assignment - Beneficiaries should be permitted and encouraged to attest to ACO assignment for the reasons discussed above;
- b. Permit beneficiaries to share in shared savings - This would encourage beneficiary alignment with an ACO and support the beneficiaries receiving care within the ACO; as well as encourage beneficiaries to align with more efficient providers.
- c. Limit quality metrics, particularly those related to payment, to those clearly identifiable as relating to the outcomes of improving care and lowering cost for the medically complex population;
- d. Establish local benchmarks - For the reasons discussed above that for a population susceptible to “high churn” it is reasonable to be compared to a local matched fee for service population that is not receiving care within this risk option ACO;
- e. Risk adjustment – Related to the benchmark and based on analysis shared with CMS regarding IAH shared savings calculations. CMS should use the V21 HCC model with a locally determined adjuster from calibration to locally assembled controls. This option would not need to be rebased nor have structured term limits to ACO agreement as with the other tracks, as again, for this high risk population the comparison is to the non assigned fee for service control population. Accurate risk adjustment will also provide confidence of the ACOs to increase the number of medically complex beneficiaries they are able to manage (without having to be concerned about underestimate of projected cost);
- f. Performance requirement /minimum savings requirement (MSR), in lieu of structured track terms. This is similar in concept to IAH though at lowered rate due to lowered medical complexity/expected cost. CMS could establish an MSR beyond which the ACO keeps the savings share. Moreover, to encourage the participation of additional ACOs of varying sizes (and the evidence from ACO experience to date is that small flexible ACOs are as capable or more as large and system based ACOs to achieve savings), CMS should consider a fixed MSR and simply recoup this savings as an automatic function. This is respectful, as reflected in the IAH model to first provide savings to the Medicare Trust Funds, encourages participation and innovation by a variety of sized and modeled ACOs, and serves to encourage year over year performance as the ACO has shared savings opportunity relative to the non ACO population. This underscores the importance of accurate risk adjustment for the medically complex, high risk population;
- g. Waivers – each of the waivers for the reasons discussed below should also be available to this ACO risk option. And the wavers are all the more relevant to improve care and lower cost for the medically complex population.

The Academy looks forward to the opportunity to discuss in detail how the results of IAH and the value of housecalls can inform ACO expansion and the development of Alternative Performance Based Risk Options.

Also, as we move on to comments in agreement that the CMS proposed waivers can support ACOs, we want to reiterate our view in the Assignment of Medicare FFS Beneficiaries section above that providers should be able to participate in multiple shared savings programs. This is also supported through the CMS understanding that individual disease and population target efforts at the provider level within ACOs needs to be supported for ACO success and to meet the triple aim. ACOs, overall, are organized to meet the triple aim. However, they may also contain sub-parts that have specific population focus that is also of CMS interest and initiative such as IAH. CMS should do all that it can to reinforce the efforts at the provider level to contribute to the triple aim. This also supports your interest in transforming the clinical community across the country. Permitting providers to participate in multiple SSPs will help you to achieve this result by enabling providers to render service that contributes to beneficiaries regardless of the ACO/SSP to which they are assigned and that is best for them. This will also permit organizations/providers to add resources and focus their sub-parts to specific populations that produce meaningful results such as IAH. The waivers the CMS proposes will go a long way to support the triple aim targeting of the home limited high risk high cost population.

3. Provisions regarding waivers of 3-day rule for SNF, post acute referrals, homebound definition, comments for the CMS consideration regarding Telehealth and recommendation to develop Part B coverage and payment for home infusion.

The Academy supports the proposed waivers as discussed in the answers to the questions the CMS presented in the Proposed Rule.

SNF – Waiver of 3 Day Rule

- Q. Whether it is necessary to provide for a waiver under their section 1899(f) authority of the SNF 3-day rule for MSSP ACOs in two-sided risk arrangements and what uniform criteria would be appropriate to determine waiver eligibility under the program?
- A. Waivers under section 1899(f) are desired and necessary for the MSSP ACOs (and assigned beneficiaries) to have the best opportunity to achieve clinical and financial success. Operating an innovative model under the payment rules from legacy Medicare program will hinder ACOs ability to succeed. ACO participants with informed beneficiary agreement need to have the flexibility to make the best clinical setting placement for the beneficiary without consideration to whether a coverage restriction from traditional Medicare has been satisfied. This would tie an ACOs hands. Moreover, it has been documented by the OIG, MedPAC and other reviewers that the adherence itself to the 3 day rule produces misuse, if not abuse, of the Part A program in terms of beneficiaries being maintained as a hospital inpatient despite medical contraindication (and despite the beneficiary site of care preferences) to satisfy the 3-day rule.
- Q. Whether or not it would be appropriate to apply the same criteria used under the Pioneer model?
- A. Yes, it would be appropriate to apply the same criteria such as participation with the ACO and meeting at least 3 Stars in Medicare’s Five-Star Quality Rating System.

Q. What specific activities should be monitored to ensure items and services are properly delivered to eligible patients; that patients are not being discharged prematurely to SNFs, and that patients are able to exercise freedom of choice and are not being steered inappropriately?

A. Clinical criteria:

- medically stable;
- clear and confirmed diagnosis;
- does not require/further hospital-based evaluation and treatment; and
- has a defined skilled or rehab need (with a clear endpoint) that cannot be provided in a home setting.

Beneficiaries would have option to remain in the hospital if hospitalized with the understanding of associated clinical risks and financial responsibility if their inpatient stay not approved.

Q. Other considerations: potential impact on access to SNF services;

A. Access to SNF services would be expected to incrementally increase. However, this would be as a substitution for more expensive/risky/traumatic hospitalization.

Q. The beneficiary assignment process;

A. ACO participants are considered to have a large primary care provider network that together with facility participants would have established SNF relationships. As a result, it is not anticipated that waiver of the 3-day rule would have material impact on beneficiary assignment.

Q. Quality measures and operational issues;

A. ACO – there is growing basis of clinical and operational experience in the ACO/health care operations community regarding waivers such as the 3-day rule. There is a growing literature base regarding the 3-day waiver. As a result, while implementing a new model of scale will always produce issues to address, it is not expected that the 3-day rule waiver will be operationally troublesome for ACOs and that the benefits of the waiver will outweigh the costs.

CMS – CMS similarly has experience through MSSP and other models with clinical and administrative matters related to waivers of the 3-day rule. CMS can rely upon this experience in application to ACOs requesting the waiver under these proposed rules. As a result, we do not anticipate that operationalizing the waiver under these proposed rules will produce other than manageable issues to CMS.

Telehealth Waiver

What factors CMS should consider if they were to provide for such a waiver to allow a broader range of Telehealth services or services in a broader range of geographic areas:

Q. How should “Telehealth” be defined?

A. The use of electronic information and communications technologies to provide and support health care when distance separates participants.

Q. Under what circumstances should payment for Telehealth and related services be made?

A. CMS should make payment for Telehealth and related services, in addition to the existing approved originating sites when:

1. The beneficiary cannot access community level primary and specialty care due to conditions that render the beneficiary home limited sufficient for the coverage and payment of a home visit; and
2. When clinically relevant under general circumstances that make Telehealth part of the community standard/medical mainstream of practice.
3. Expand the rural definition to HPSA and underserved urban populations.

Q. What types of services should be included (remote monitoring, remote visits, and/or e-consults)?

A. There should be no prescribed limitation to the types of services, rather the types of services that would be understood as being those accepted as the community standard if the beneficiary was able to access services in any other setting of care as any other beneficiary is able to do.

The medical circumstances and condition of the beneficiary would define the services needed and the beneficiary would be able to receive such services as defined by their circumstances to the extent that technology supports an otherwise community standard provision of care.

Q. What capabilities or additional criteria should ACOs meet to qualify for payments for Telehealth services under the waiver?

A. ACOs should have to meet the existing technology standards for Telehealth and should demonstrate that they are able to provide a medical (MD, DO, NP, PA) encounter/intervention – e.g., home visit) or have the ability to bring the beneficiary to an ACO location for such encounter if indicated by Telehealth services.

Q. Any quality and outcomes metrics that may be impacted or should be considered:

A. The same quality and outcomes metrics should be applied to Telehealth services under the waiver as would be applied if the services were rendered in person, and under any other model of health care delivery.

Q. Requirements to ensure protection of beneficiaries and the Medicare Trust Funds:

A. Medicare's existing fraud abuse provisions, holding services rendered through Telehealth to the same quality and outcomes standards, medical ethics, licensure, and professional liability standards on a state and local level will serve to protect beneficiaries and the Medicare Trust Funds.

Q. Any other design factors of importance?

A. Important to match the Telehealth services with the patient population receiving service. Telehealth, cannot be considered as a substitute, for example, for the in-person evaluation and

management of cognitively impaired beneficiaries of any age and is often the case of the frail elderly living in isolated circumstances. Over time CMS should develop, in conjunction with the medical community, guidance regarding the use of Telehealth and the requirements for in person medical care. This would be informed by evidence based findings as the services of ACOs grow and also based on advances in Telehealth.

Homebound Requirement under the Home Health Benefit

CMS proposes waiving the "home-bound" or the "confined to the home" requirement such that Medicare would pay for non-home-bound ACO beneficiaries to receive home health services. CMS proposes to limit the waiver to Track 3 ACOs or to ACOs participating in a two-sided risk track. The Academy supports the waiver and moreover, we support the use and benefit of this waiver for all ACO tracks and SSP programs including Independence at Home, as discussed further below.

This waiver as well as the others proposed would:

- Expand the benefits of ACOs and other models with home care medicine capacity and contribute to the Triple Aim;
- Modernize Medicare from its historic (Part A, B, C, D) programmatic roots and regulation;
- Enhance and support medically led, team based decision making that incorporates and respects beneficiary preferences in terms of setting of care; and
- Encourage the development of home care medicine workforce necessary to meet the needs of the 3-4 million of Medicare beneficiaries who would benefit from home care medicine services.

CMS cites its Independence at Home (IAH) demonstration that provides non-home-bound Medicare beneficiaries home-based primary care services. The IAH demonstration has basis in the VA's Home-Based Primary Care program (HBPC) and the HBPC program has been a triple aim success. The HBPC program has reduced the patient overall cost of care by 24% (\$38,000 v. \$29,000). It has reduced hospital cost of care by 63% (\$18,000 v. \$7,000) and nursing home care by 87% (\$10,000 v. \$1,400). The program also has high beneficiary and caregiver satisfaction.

More recent evidence of the benefits that expanded availability of housecalls (and further the opportunity to add the cost avoiding impact of the "homebound" waiver) would produce are found in Medicare Advantage results, in Medicaid dual eligible programs, in ACO results that CMS analysis of those receiving IAH-like/IAH managed housecalls vs. those not receiving such housecalls (16% percent ACO self-reported savings to Academy), and also seen recently published of the 17% reduction in total Medicare costs for Home-Based Primary care patients, with average reduction of over \$4000 per patient per year. This is from the five-year study of Medicare costs and survival in a home-based primary care practice serving (IAH-like) ill and high-cost elders in Washington DC that was published in the Journal of the American Geriatric Society. "Effects of Home-Based Primary Care on Medicare Costs in High-Risk Elders" <http://onlinelibrary.wiley.com/doi/10.1111/jgs.12974/abstract>

The cited evidence provides that team based home care medicine programs are making significant medically supported substitution of other sites of care and services to avoid the multiple (financial, psychological, physical, etc.) costs of hospital admissions and readmissions.

We anticipate that the results the CMS cites in seeking comments of "how could the findings from Independence at Home (IAH) demonstration apply to the population of beneficiaries assigned to ACOs

or receiving care furnished by ACO providers/suppliers” will add relevant Medicare Part B evidence to that cited above of the benefits of home care medicine programs. As a result, their development should be encouraged across ACOs and through a continuation and expansion of IAH.

How the Academy Involvement with ACOs and IAH Can Assist CMS with the Waiver

As mentioned Academy members participate with ACOs and each IAH demonstration practice is also an Academy member. The Academy conducts, and CMS participates, in a grant funded IAH Learning Collaborative to identify and replicate best practices and lessons learned. The Academy is conducting its 4th IAH Day on May 13 immediately preceding the Academy Annual Meeting. Based on the Academy deep involvement with ACOs and IAH we propose;

1. The Academy use the IAH Day attended by those with clinical and administrative expertise with the home limited population, post acute settings, and ACO/IAH experience to develop beneficiary relevant clinical vignettes as case examples reflecting the care of beneficiaries without the waivers and with the waivers in place.
2. The Academy meet with CMS staff who would be responsible for drafting the regulations to implement the waivers to share the discussion of how care and cost compares without the waivers and with the proposed waivers. CMS would then have detailed operational recommendations to use in its development of regulations implementing the waivers across its shared savings programs.

Q. How could the findings from Independence at Home (IAH) demonstration apply to the population of beneficiaries assigned to ACOs or receiving care furnished by ACO providers/suppliers?

A. IAH techniques to care for high risk high cost patients have been used by as discussed above by organizations operating or arranging housecalls in ACOs, Medicare Advantage and duals health plans.

Based on these results and those CMS has identified and will publicize for IAH, it is important for ACO success and the care of the high cost high risk beneficiaries for:

1. the waiver to be established; and
2. essential that ACOs of all tracks, other SSPs, and Medicare payment models with triple aim incentives be encouraged to adopt medically led team based home visit programs.

The Academy would be pleased to work with CMS to develop guidelines regarding home visit practices and strategies bases on the successful experience in ACOs and IAH as you have indicated to incorporate home visit programs into ACOs and across other triple aim models.

Specifically, the IAH findings/techniques and incorporated home visit practices would be used when ACOs conduct beneficiary assessments and find that the assigned beneficiary/one receiving care, furnished by an ACO provider or supplier, satisfies clinical criteria similar to that established for IAH. Then, the beneficiary would be “sub-assigned” to the home visit program of the ACO to manage the care. This assignment would be discussed with the beneficiary for their agreement and noted in medical records as well as in the ACO system for care coordination.

We also want to use this opportunity to contribute our assistance to the CMS to eliminate confusion that may exist in the general healthcare community of providers and agencies, as well as Medicare contractors, that a beneficiary has to be homebound to receive a housecall. The implementation of the waiver would serve as an appropriate and important opportunity to eliminate this confusion.

- Q. What criteria would be appropriate to determine eligibility for the waiver? If there are specific categories of providers or beneficiaries to whom the waiver should (or should not) apply.
- A. Beneficiaries meet the Medicare Part B medical necessity requirements for a house call (in lieu of an office visit). The criteria are the combination of the Social Security Act definition of Medical Necessity and the coverage and payment for home visits as established in the Social Security Act and Medicare Carriers Manual 30.6.14.1 Home Services (Codes 99341-99350). Beneficiaries should reflect the Part B medical necessity need of a home health service that otherwise would not have been available unless the beneficiary met the Part A homebound definition.

Providers should have to meet one of the following criteria:

1. experience as reflected in Part B, housecalls (at least 50 in past year) in the Medicare Part B claims database on a date prior to ACO approval; or
2. evidence of competency in housecalls demonstrated through training: membership in the American Academy of Home Care Medicine (Academy) or certification as a home care medicine provider through standards approved or developed by the Academy.

Additionally, and for operational purposes, the CMS may want to consider development of pre-admission discretionary assignment of LUPA (or similar) status for home health services that may not relate to a 60-day episode. This approach to waiver implementation could serve as one among others. The Academy has signed onto a letter of the American Medical Association (AMA) that discusses this aspect in more detail.

- Q. If implemented under a two-sided risk model, are there additional protections for the Medicare Trust Funds or for beneficiaries that should be considered?
- A. The protections under the existing Medicare fraud and abuse and related medical record review programs are sufficient protection for the Medicare Trust Funds. This includes the review of HHA documentation and the medical record documentation of the “certifying physician” that the home health services were medically necessary. Additional protection can be considered if circumstances warrant.
- Q. What quality metrics should be incorporated into the quality measure framework for ACOs and CMS’s monitoring program to measure the quality of care for non-homebound home health recipients?
- A. Beneficiaries - The quality measures required of ACOs serve as a beneficiary protection. Additionally, CMS could consider the quality measures of the IAH demonstration that are not tied directly to payment though are tied to practice evaluation. These measures include:
- Beneficiary/caregiver goals
 - Screenings/assessments
 - Symptom management

- Medication management
- Caregiver stress
- Voluntary disenrollment rate
- Referrals
- Patient satisfaction

The measures tied to payment are less relevant as they relate to admissions that may have not occurred and are hoped to decrease through the increased availability of a home visit.

Q. How would a waiver complement Medicare payment for physician home visits for medically complex patients?

A. A waiver would:

- Complement Medicare payment for physician home visits for medically complex patients in many ways;
- Provide payer model encouragement to increase the workforce available to provide home visits and also send this signal to other payers;
- Encourage more thorough assessment of beneficiaries and the opportunities for beneficiaries to receive care and needed services in the home;
- Support quality improvement in the workforce available to provide home visits;
- Support efforts to maintain the beneficiary in their home and avoid hospitalizations and other more costly sites of care;
- Encourage payers, in addition to the ACOs; to develop home visit capacity within their organization or create relationship with the ACO home care medicine practice(s). This will replicate the benefits of home care visits in other settings in addition to the ACO and provide for improved care and program savings.

Estimates are that only 15.5% of beneficiaries in need of home visits receive them. It is also known that this home limited beneficiary population is part of the 5% of beneficiaries that explain approximately half of the Medicare program cost.

The findings of IAH (not publically available to commentators at the due day of these comments, if consistent with the growing evidence base from VA, ACOs and other published articles discussing IAH type care), are anticipated to reflect that the availability and provision of IAH home visits has material impact on Medicare program cost through reduced facility service utilization while improving care and increasing beneficiary and caregiver satisfaction. These findings support the waiver and the expansion of home visits across the country.

Additionally, the waiver will provide an opportunity to work with CMS to eliminate the residual confusion (that dampens the expansion of home visits and its benefits), that beneficiaries need to be homebound to be eligible for a Part B home visit.

Q. What considerations, if any, should CMS take into account when adapting current 60-day episode payment amounts that require patients to be homebound in applying them to services furnished to a non-homebound population?

- A. Beneficiaries should meet the Medicare Part B medical necessity requirements for a house call (in lieu of an office visit), and CMS could with agreement of select ACOs begin to demonstrate within this MSSP with payment models that are reflective of the types and intensities of HHA services ordered (versus paying the 60 day episode). This will provide CMS and the participating ACOs additional information regarding the impact of the waiver and best approaches to payment.

CMS should consider payment for medically directed nurse monitoring for this population. This could be part of a basis of payment that builds upon the chronic care management code (CPT 99490), and supports Medicare policy to pay for additional chronic care management.

CMS could also begin to evaluate these payment alternatives (including nurse monitoring) in other Medicare demonstrations such as Independence at Home.

- Q. When should the waiver be applied?

- A. The waiver would apply when the ACO application is approved as a general matter. The waiver would be applied when the ACO (participant) determines that a beneficiary may not be homebound but does meet the Part B medical necessity requirements for a Part B visit and moreover reflects the medical need for a home health service. We discuss other implementation considerations throughout this section.

Medicare would maintain coverage and payment for certification/re-certification and care plan oversight as these services would continue to be provided. The TCM and CCM services/codes would also be used to manage beneficiaries care and with recognition that only one service by one provider will be paid as appropriate per code service period.

- Q. Would there be specific circumstances when home health services should be available at any point without first being triggered by some health event?

- A. Patient and environmental assessment including physical environment and caregiver capacity should drive when home health service is needed. And under the same circumstances for the determination under that home health is indicated other than the beneficiary not meeting the exact Part A definition of homebound.

- Q. If so, what criteria would be necessary to differentiate these circumstances from non-covered custodial care?

- A. This would require physician led care team decision that the beneficiary due to relationship of non-medical issues to a medical condition, was at risk of utilizing more intensive health services and that addressing the non medical issues could eliminate the potential use of expensive and otherwise medically unnecessary services.

Waivers for Referrals to Post-acute Care Settings

- Q. Are there other cost and quality criteria that should be considered?

- A. CMS could establish consistent as with the SNF wavier meeting at least 3 Stars in Medicare's Five-Star Quality Rating System.

Additionally, criteria should be considered as adopted by the medical community. For example, were there to be an evidence base that one post acute setting/pathway provided superior results for a beneficiary's condition (DRG/ICD) as compared to other settings, then this type of evidence, as developed, should be added to that permitted to be shared with the beneficiary.

This evidence could include outcomes such as the likelihood of readmission for same condition, or for unrelated condition as compared to:

1. other providers of the same post acute services and,
2. other types of post acute providers.

This evidence could also include total cost of episode in conjunction with the outcome data.

- Q. To what hospitals and post-hospital providers should the waiver apply (e.g., should the ability to recommend a post-hospital provider be available only to those hospitals that are ACO participants or ACO providers/suppliers);
- A. Initially, the waiver should only apply to hospitals that are ACO participants (unless there is found to be a shortage of willing quality and cost effective post acute providers). This is appropriate as there is a context to the waiver and program criteria to be met. Based on analysis of the results of hospitals in the ACO MSSP vs. non ACO hospitals, then CMS can consider expanding the waiver to non waiver hospitals.
- Q. Should a hospital be permitted to recommend any post-hospital provider, or only post-hospital providers that are ACO participants or ACO providers/suppliers (CMS anticipates that if a waiver is found to be necessary, it would apply to all hospitals that are ACO participants or ACO providers/suppliers and that they would have the ability to recommend any post-hospital provider, but they would be interested to receive comments on alternative approaches);
- A. Hospitals should be permitted to apply the waiver to any post-hospital provider. Hospitals will naturally have considered cost and quality when establishing their ACO. However, there may be performance of a post hospital provider that is beneficial for the beneficiary and also the ACO and for one reason or another did not join the ACO.

While it is anticipated that the use of non-ACO providers would be the exception, and that it is important for care coordination (protocols, IT, EHR, etc.) to work with participating providers/suppliers in one's ACO/network, this freedom to apply the waiver to non-ACO providers/suppliers will also help to maintain a competitive market in the ACO community for post hospital providers. This should also serve to create spillover benefits for beneficiaries in the community that are not assigned to the ACO and also serve to improve the performance of the post hospital environment for Medicare.

- Q. Are there other parameters that should be established around how hospitals formulate their lists of post-acute providers?

- A. The requirements that beneficiaries retain choice as provided in the proposed rule and that reasonable geographic access for beneficiaries is maintained.
- Q. What information should be shared with beneficiaries (e.g., only quality information that is publically reported, such as Home Health Compare, or would internally generated information also be appropriate)?
- A. The following information should be provided to beneficiaries:
- Information that is publically reported should be shared;
 - Peer reviewed (and similar level) information that is developed around the services should be shared; and
 - Internally generated information focused on the same conditions for which the beneficiary is being referred.
- Q. Whether it would be feasible to implement a system where the CoP requirement to not make recommendations is waived for the ACO participating hospitals only in the case of certain Medicare FFS beneficiaries?
- A. This should not be the basis of the waiver at the onset and should be considered only as supported through ACO performance with the waiver around the country with enough beneficiaries to be scientifically valid, or to have identified issues that are systemic to the waiver and not to the operations of specific ACOs.
- Q. Whether waiving this portion of the regulation for ACO participating hospitals with respect to all their patients might be necessary for carrying out the MSSP and what benefits and risks might arise for non-Medicare patients?
- A. The waiver will be a necessary support to the success of the MSSP. Benefits to non-Medicare patients are as described above – maintenance of competition by permitting hospitals to refer both within and outside of the ACO will provide quality and cost protection to Medicare beneficiaries assigned to the ACO and not assigned to the ACO. Non-Medicare patients should also benefit through the influence of the ACO and the waiver. This should encourage an environment of continuous quality improvement in the community.
- Q. Whether it would be appropriate to limit any such waiver to ACOs participating under two-sided risk models or whether such a waiver should be available more broadly to all MSSP participants?
- A. The waiver should be available to all MSSP participants. CMS is interested through this regulation and other initiatives in transforming the provider community to shared savings and value based models. It is understood that the more beneficiaries/patients that are involved in a payment model the greater the ability to support changes in behavior, cost effectiveness and transformation.

Moreover, ACOs should be encouraged to establish their ACO suppliers/providers relationships based on quality and cost. This would not be different based on the experience of the ACO or whether they are involved on a one or 2-sided basis. At an operational level, with ACOs and to the extent there is movement of staff from one hospital/ACO to another, the familiarity of staff with the waiver will be beneficial in the healthcare delivery marketplace under transformation.

As a result, it will benefit beneficiaries, ACOs, the post acute providers (through incentive to improve performance), and Medicare to apply the waiver to all MSSP participants.

- Q. Whether, alternatively, the waiver should apply only to beneficiaries prospectively assigned under proposed Track 3:
- A. The waiver should apply to all Tracks as discussed above.
- Q. What operational considerations/concerns implementation of such a waiver might raise; and what additional beneficiary protections should be considered and put in place to prevent abuse.
- A. The existing freedom of choice, fraud and abuse, and licensure protections that would apply to the other waivers should apply as CMS discusses in the proposed rule. Also, the information to be shared with beneficiaries, as discussed above, will provide beneficiary protection.

Waiver of Other Payment Rules

CMS seeks comment on the waiver of the other payment rules that would support ACO participation and success. The Academy for the reasons discussed above in terms of increasing ACO flexibility, modernizing the regulatory environment and meeting the Triple Aim recommends 1) wavier of certain hospice provisions, and 2) addition of Part B coverage and payment for home infusion.

Waiver of Certain Hospice Provisions

- CMS should develop provisions that reduce the hospice conditions of payment provisions with relationship to limits to the amount of beneficiary expense.
- ACO (and other SSP), beneficiaries should be excluded from the hospice cap penalty calculation.
- The offering of hospice benefits should be at the discretion of the ACO (or other SSP).

Coverage and Payment for Home Infusion Services

CMS should establish coverage and payment under Part B for home infusion services arranged by ACOs and other MSSPs.

Medicare covers infusion therapy in offices and institutional settings. Studies estimate that 23% of beneficiaries receiving antibiotic infusions would begin receiving services in the home setting if Medicare adequately covered infusion in the home. Estimated savings to the Medicare program for the 10-year period from 2015 to 2024 are \$80 million (12.6%), of the overall cost of infusion services that would migrate from HOPDs, physician offices, and SNFs to the home. This does not include travel cost and inconvenience to beneficiaries. This also does not include potential additional savings that could result from the avoidance of hospital stays, hospital-acquired infections and SNF admissions.

Under this waiver Medicare Part B should cover the professional services, including nursing services (other than nursing services covered as home health services), administrative, compounding, dispensing, distribution, clinical monitoring, and care coordination services that are necessary for the provision of infusion therapy in the home.

Part B payment would also cover all necessary supplies and equipment (i.e., medical supplies such as sterile tubing and infusion pumps) as well as other items and services that the Secretary of the Department of Health and Human Services deems necessary to administer infusion drug therapies safely and effectively in a patient's home.

Home infusion therapy providers would need to be accredited and would include any pharmacy, physician, or other provider licensed by the State in which the pharmacy, physician, or provider resides or provides services, whose State authorized scope of practice includes dispensing authority, and that:

1. Has expertise in the preparation of parenteral medications in compliance with enforceable standards of the U.S. Pharmacopoeia and other nationally recognized standards that regulate preparation of parenteral medications as determined by the Secretary and meets such standards;
2. provides infusion therapy to patients with acute or chronic conditions requiring parenteral administration of drugs and biologicals administered through catheters or needles, or both, in a home; and
3. meets such other uniform requirements as the Secretary of Health and Human Services determines are necessary to ensure the safe and effective provision and administration of home infusion therapy on a 7 day a week, 24 hour basis (taking into account the standards of care for home infusion therapy established by Medicare Advantage plans and in the private sector), and the efficient administration of the home infusion therapy benefit.

The Academy appreciates the opportunity to comment, and we would be pleased to answer any questions.

Sincerely,



Robert Sowislo
Chair, Public Policy Committee