SUMMARY CHART OF PROPOSED AMENDMENTS TO 42 C.F.R. PART 425 GOVERNING THE MEDICARE SHARED SAVINGS PROGRAM

Regulatory Cite in C.F.R. Title 42	Description of the Proposed Amendment	Potential Impact
Subpart A—General Provisions		
§ 425.20 (amended)	*ACO participant and ACO provider/supplier* (amended) – CMS proposes to amend these two definitions to resolve existing confusion. ACO participant – CMS proposes to clarify that an ACO participant is an entity identified by a Medicare-enrolled TIN, as opposed to a practitioner. ACO provider/supplier – CMS proposes to clarify that an individual or entity is an ACO provider/supplier only when it bills for items and services furnished to Medicare fee-for-service (FFS) beneficiaries during the agreement period and is included on the list of ACO provider/suppliers that is required under the proposed regulation at § 425.118. This proposed amendment clarifies that a provider or supplier must bill for items or services furnished to Medicare FFS beneficiaries through the TIN of an ACO participant during the ACO's agreement period in order to be an ACO provider/supplier.	The majority of these amendments to the definitions would clarify areas of previous confusion identified by CMS. Other changes to the definitions would coincide with broader policy changes to the Medicare Shared Savings Program (MSSP) (*e.g.,* the expansion of the definition of primary care services).
	ACO professional (amended) – CMS proposes to remove the requirement that an ACO professional be an ACO provider/supplier and clarifies that an ACO professional is an individual who bills for items or services he or she furnishes to Medicare FFS beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant. The rationale is that there might be ACO professionals who bill using the TIN during the benchmarking years, but are no longer affiliated with the ACO participant and, therefore, not providing services during the performance years.	
	ACO participant agreement (new) – CMS proposes to define an ACO participant agreement to mean the written agreement (as required at § 425.116) between the ACO and ACO participant in which the ACO participant agrees to participate in, and comply with, the requirements of the MSSP. CMS would make conforming amendments to other relevant provisions in Part 425 that reference "ACO agreements."	
	Agreement period (amended) – CMS proposes to define the ACO's agreement period to be 3 performance years "unless otherwise specified in the agreement." This amendment takes into account the possibility of an ACO renewing its participation agreement.	
	Assignment (amended) – CMS proposes to delete the reference to "a physician who is an ACO provider/supplier" and substitute "ACO professionals," given the amended definition of "ACO professional."	
	Assignment window (new) – CMS proposes to define assignment window to mean the 12-month period used to assign beneficiaries to an ACO.	
	Continuously assigned beneficiary (amended) – CMS proposes to amend this definition to read: "*Continuously assigned beneficiary* means a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year."	

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	Hospital (amended) – CMS proposes to define "hospital" as it is defined in § 1886(d)(1)(B) of the Act. CMS notes that the proposed text is more consistent with the statutory definition of "hospital" for purposes of the MSSP in § 1899(h)(2) of the Act. This amendment also clarifies that Maryland acute care hospitals are "hospitals" for purposes of the MSSP. (Under the previous definition, it could be interpreted that Maryland hospitals are not hospitals because they have a waiver and are not subject to the PPS.)	
	Newly assigned beneficiary (amended) – CMS proposes to change this definition in light of the new definition for *assignment window.* The amended definition will read: "*Newly assigned beneficiary* means a beneficiary that is assigned to the ACO in the current performance year who was neither assigned to nor received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year."	
	Participation agreement (new) – CMS proposes to add a new definition of *participation agreement* to mean the written agreement required under § 425.208(a) between the ACO and CMS that, together with the regulations at Part 425, governs the ACO's participation in the MSSP.	
	Primary care services (amended) – CMS proposes to expand this definition so that primary care services include CPT codes 99495 and 99496, HCPCS code GXXX1, and additional codes designated by CMS as primary care services for purposes of the Shared Savings Program, including new HCPCS/CPT and revenue center codes and any subsequently modified or replacement codes for the HCPCS/CPT and revenue center codes.	
Subpart B—Shared Savings Program Eligibility Requirements		
§ 425.104(a) (amended)	CMS proposes to clarify that the governing body must meet the following criteria: 1) the governing body of the ACO must be the same as the governing body of the legal entity that is the ACO; 2) in the case of an ACO that comprises multiple ACO participants, the governing body must be separate and unique to the ACO and must not be the same as the governing body of any ACO participant; and 3) the governing body must satisfy all other requirements set forth in § 425.106.	This amendment would reduce the flexibility of ACOs to pursue innovative governing structures. CMS is specifically seeking comment on the first criterion. CMS's stated reason for this amendment is to preclude delegation of the ACO's decision making authority to a committee and to preclude retention of this power by a parent company.
§ 425.104(b) (amended)	CMS proposes to remove the reference to "otherwise independent ACO participants" in this section due to confusion, and it will clarify that "two or more ACO participants, each of which is identified by a unique TIN, must be a legal entity separate from any of its ACO participants." CMS also proposes deleting § 425.104(b)(4) and § 425.104(b)(5) as these matters are addressed in the revisions of § 425.104(a).	This amendment is prescriptive and may reduce the flexibility of ACOs to pursue innovative governing structures.
§ 425.106(b)(3) (amended)	CMS proposes to clarify that the fiduciary duty owed to an ACO by its governing body members includes the duty of loyalty.	This amendment would not reflect a change of policy, only a clarification.

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§ 425.106(c)(1) (amended)	CMS proposes to reiterate the requirement that ACOs have "a mechanism for shared governance" among participants.	This amendment would not result in a change in policy; it is aligning the regulations with the statutory requirements.
§ 425.106(c)(2) (amended)	CMS proposes to explicitly prohibit an ACO provider/supplier from being a beneficiary representative on the ACO' governing body. CMS retains flexibility around the requirement that a beneficiary representative must be on the governing body when such action may run afoul of Corporate Practice of Medicine laws.	This amendment would reflect CMS's conclusion that an ACO provider/supplier's incentives may be misaligned with those of beneficiaries. ACOs may find this to be an unwarranted generalization.
§ 425.106(c)(5) (amended)	CMS proposes to remove the flexibility for ACOs to request a deviation from the requirement that at least 75% control of an ACO's governing body be held by ACO participants.	This amendment would reduce the flexibility of ACOs to pursue innovative governing structures, but CMS noted that no applicant has struggled to reach the 75% threshold, so this amendment should have minimal impact.
§ 425.108(c) (amended)	CMS proposes to amend this section to either remove the requirement that the medical director must be an ACO provider/supplier or retain the requirement and permit ACOs to request CMS approval to designate a medical director who is not an ACO provider/supplier. CMS also proposes to clarify that the medical director must be physically present on a regular basis at any clinic, office, or other location of the ACO, ACO participant, or ACO provider/supplier.	This amendment would provide ACOs with more flexibility to appoint a medical director who is not aligned with the ACO as a participant or provider/supplier. Still, ACO medical directors would have more stringent presence requirements, which may make them harder to recruit or retain.
§ 425.108(e) (delete)	CMS proposes to delete this provision, which currently provides for flexibility to request an exception to the leadership and management requirements. CMS proposes this deletion because it believes flexibility is only necessary for the medical director, which would be retained in the proposed amendment to § 425.108(c).	This amendment would reduce the flexibility of ACOs to pursue innovative governing structures.
§ 425.110(a)(2) (amended)	CMS proposes to clarify that the number of assigned beneficiaries would be calculated for each benchmark year using the assignment methodology set forth in Subpart E of Part 425, and in the case of the third benchmark year, CMS would use the most recent data available with up to a 3-month claims run out to estimate the number of assigned beneficiaries.	This amendment would likely prompt ACOs to disagree with CMS's notion this change is consistent with how CMS has completed the estimates for current MSSP ACOs, after considering the changes to the information that CMS would provide in the amended beneficiary assignment process described in §§ 425.400 through 425.404.
§ 425.110(b) (amended)	CMS proposes to change the "will" in this section to "may" to provide itself with more flexibility and discretion regarding when to issue a Corrective Action Plan (CAP) when the ACO's assigned population falls below 5,000. CMS further proposes to remove the requirement in § 425.110(b)(2) that states, when an ACO falls below 5,000 assigned beneficiaries, the CAP requires it to increase its assigned beneficiary population to at least 5,000 by the end of the next performance year or be terminated. Instead, CMS proposes that it would set the timeframe in the CAP by which the ACO's assigned population must meet or exceed 5,000 beneficiaries.	This amendment would provide CMS with greater flexibility on issuing CAPs in instances where an ACO temporarily falls below 5,000 participants. In addition, the change to § 425.110(b)(2) allows CMS to provide ACOs with more time to enter new ACO participant TINs and/or ACO provider/suppliers under such TINs to increase the number of assigned beneficiaries.

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§ 425.112(b)(4)(ii)(C) (new)	CMS proposes to add this new requirement as part of the application in which the ACO applicant must describe how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries, such as electronic health records, telehealth, or other electronic tools to engage patients in their care.	This new provision would clarify CMS's position on encouraging ACOs' use of telehealth and other electronic tools to better care coordination efforts.
§ 425.112(b)(4)(ii)(D) (new)	CMS proposes to require the ACO applicant to describe how it intends to partner with long-term care and post-acute care providers.	This new provision would clarify CMS's position on collaborations with post-acute care providers.
§ 425.112(b)(4)(ii)(E) (new)	CMS proposes to add this new provision requiring the applicant to define and submit reports on major milestones or performance targets.	This new provision would allow ACOs to have opportunities to define their own milestones for success and provide input to CMS on realistic goals.
§ 425.116 (new)	CMS proposes to add this section to codify and supplement its previously stated requirements for ACO participant agreements among the ACO and its ACO participating providers/suppliers. Specific requirements for the ACO participant agreements include: • The ACO and the ACO participant are the only parties to the agreement. • The agreement must be signed by individuals authorized to bind the ACO and the ACO participant. • The agreement must expressly require the ACO participants to agree and to ensure that each ACO provider/supplier agrees to participate and comply with relevant laws and regulations. • The agreement must set forth the ACO participant's rights and obligations in, and representation by, the ACO. • The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO. • The agreement must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers. • The term of the agreement must be for at least 1 performance year and must articulate potential consequences for early termination from the ACO. • The agreement must require completion of a close-out process upon the termination or expiration of the ACO's participation agreement. CMS would require that a corresponding executed ACO participant agreement would also need to be submitted when an ACO seeks approval to add new ACO participants.	This new provision would provide a clearer set of guidelines for applicants and should clarify much of the uncertainties that led to rejections of ACO applications and, therefore, lower numbers of assigned beneficiaries.
§ 425.118(a) (new)	CMS proposes to clarify that, prior to the start of the agreement period and before each performance year thereafter, the ACO must provide CMS with a complete and certified list of its ACO participants and their Medicare-enrolled TINs. From this list, CMS would identify the NPIs of providers/suppliers billing through the ACO's TIN. Under § 425.118(a), the ACO would have to review the list and certify it is true, accurate, and complete.	This new section would provide more clarity on CMS's expectations around the ACO certified participant and provider/supplier list; it should not impose a new requirement, as §§ 425.204(c)(5) and 425.304(d) already required the certification of these lists.

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§ 425.118(b) (new)	CMS proposes to address the procedures for adding and removing ACO participants during the ACO participation agreement period. To add ACO participants, the ACO must submit a request to CMS and, if CMS approves the request, the new participant(s) will be added to the ACO participant list the following performance year. For terminations, ACO must notify CMS no later than 30 days after the date of termination of the entity's ACO participant agreement, effective the date of the termination. This section would also codify CMS's policy that, absent unusual circumstances, the removal of an ACO participant from the ACO participant list during the performance year will not affect the ACO's beneficiary assignment.	This new section would provide more clarity on CMS's expectations around the certified ACO participant and provider/supplier list and adding new ACO participants.
§ 425.118(c) (new)	CMS proposes to provide guidance on how to report changes to the ACO provider/supplier list that occur during the performance period. CMS proposes that changes must be reported within 30 days and would need to be submitted in a format determined by CMS (potentially via email or website). If the notice is given within 30 days, it would become effective on the date specified in the notice. If notice is provided after 30 days, it will be effective the date CMS receives notice. However, CMS is considering delaying the effective date of a new ACO provider/supplier until the start of the next performance year (until then, the ACO provider/supplier would be an ACO professional). To remove an ACO provider/supplier, CMS proposes the ACO must notify CMS no later than 30 days following the removal.	This new section would provide more clarity on CMS's expectations around the certified ACO participant and provider/supplier list and adding new ACO providers/suppliers.
§ 425.118(d) (new)	CMS proposes to codify the requirement that ACOs report changes in the ACO participant and ACO provider/supplier enrollment status in Provider Enrollment, Chain and Ownership System (PECOS) within 30 days after the changes occurred.	This new section would provide more clarity on CMS's expectations around the certified ACO participant and provider/supplier list.
Subpart C—Application Procedures and Participation Agreement		
§ 425.202(b) (amended)	CMS proposes to amend this provision to allow Pioneer ACOs the opportunity to apply to the MSSP using a condensed application, if the Pioneer ACO meets certain criteria.	This amendment would provide a more streamlined process to transition Pioneer ACOs to the larger MSSP.
§ 425.204(c)(5)(i)(A) (delete)	CMS proposes to delete § 425.204(c)(5)(i)(A), which requires that the ACO to indicate whether the ACO provider/supplier is a PCP as defined by § 425.20 because this information can be derived from claims.	This proposed deletion would help reduce reporting burdens on the ACOs.
§ 425.204(c)(6) (new)	CMS proposes to require that, as part of the MSSP application process and upon request by CMS thereafter, the ACO must submit documentation demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the MSSP. For ACO participants, this evidence would include executed agreements or sample form agreements together with the first and last (signature) pages of the executed agreement.	This new provision would codify and expand previous guidance. Previous guidance required that ACOs must submit the first page and signature page of the executed ACO participant agreement(s) with each ACO participant. This new provision would expand that requirement and may now require the submission of evidence that all ACO provider/suppliers and other individuals performing functions related to ACO activities are following the requirements of the MSSP. It is possible that the expansion of this provision could be burdensome to ACOs, especially depending on how CMS defines "other individuals or entities performing functions or services related to ACO activities."

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§ 425.204(g) (new)	CMS proposes to codify its current guidance on mergers and acquisitions, but would add the option for ACOs to request consideration of claims submitted by Medicare-enrolled TINs of acquired entities as part of their applications.	This provision may appease some of the ACOs that disagreed with CMS's stance on this topic.
§ 425.206(a) (amended)	CMS proposes to better articulate the application process and the meaning of the reference to "application due date." These amendments would include the requirement that all required information must be submitted by the deadlines stated by CMS during the MSSP application process and would clarify the information that CMS would use to make determinations for accepting an ACO into the MSSP.	This amendment would likely reduce the flexibility ACOs have for submitting information to CMS during the application process.
§ 425.212(a) (amended)	CMS proposes that ACOs would be subject to all regulatory changes that become effective during the MSSP agreement period, except regulations regarding certain specified program areas. This proposal would, therefore, subject ACOs to any regulatory changes regarding the beneficiary assignment processes.	This amendment would represent a reversal in current regulation; the current regulation indicates that ACOs are not subject to any regulatory changes regarding beneficiary assignment that become effective during the MSSP agreement period. This would mean ACOs are subject to changes such as those regarding ACO structure and governance and the calculation of the sharing rate upon adoption, even during an MSSP agreement period.
§ 425.214(a) (redesignated from § 425.214(b) and amended)	CMS proposes to specify that a "significant change" occurs when the ACO is no longer able to meet eligibility or other requirements of the MSSP or when the number or identity of the ACO participants changes by 50% or more during the agreement period.	This amendment would provide greater clarity on when a significant change occurs. The requirement that a significant change occurs with 50% of the ACO participants change during the agreement period, however, could be detrimental to smaller ACOs.
§ 425.214(b) (redesignated from § 425.214(c) and amended)	CMS proposes to clarify the process for identifying a "significant change." Once the ACO provides notice to CMS, CMS would evaluate it and this section would provide CMS's options, such as requesting additional information or terminating. The proposed revision also allows CMS to take action "upon becoming aware of a significant change" from the ACO. CMS is specifically seeking on comment on whether notice of certain changes (*e.g.,* Change of Ownership) should be required *prior to* the change occurring.	Through this amendment, CMS appears to be taking a more vigilant role in monitoring the operations of an ACO and will actively make its own determinations of whether the ACO merits continued participation in the MSSP during the MSSP agreement term.
§ 425.218 (amend)	CMS proposes to add two new reasons why the agency may terminate an ACO's participation agreement: (1) for failure to comply with CMS requests for documentation or other information by deadlines specified by CMS; or (2) for submitting false or fraudulent data or information.	This proposed change may make it more difficult for ACOs to negotiate timelines for submission of supplemental information. It is unclear how CMS proposes to determine if information is false or fraudulent and what standard of proof it will apply to that determination.
§ 425.220(b) (delete)	CMS proposes to remove this provision and address early termination procedures and requirements for ACOs in new § 425.221.	*See* § 425.221 comments.
§ 425.221 (new)	CMS proposes to create specific close-out procedures for ACOs that terminate their MSSP participation agreements with CMS before the end of the three-year participation period governing notice to ACO	This new section would provide ACOs with more clarity on the expectations and consequences of terminating an MSSP

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	participants, record retention, data sharing, quality reporting, beneficiary continuity of care, and other relevant operational matters previously established through sub-regulatory guidance. This new section would also clarify that terminating an MSSP ACO participation agreement before the end of a performance period (*e.g.,* December 31st of that year) would result in the MSSP ACO forfeiting any shared savings that it may have earned and that failing to complete the close-out process as CMS requires would also result in forfeiture of those savings.	agreement with CMS early.
§ 425.222(c) (amended)	CMS proposes to allow terminated ACOs to reapply to the MSSP in a subsequent agreement period. Whether an ACO that reapplies to the MSSP would be considered to be in its first or second agreement period would depend on whether the termination occurred before or after the half-way point of a three-year agreement period. ACOs that previously applied under the two-sided risk model would only be able to reapply to participate under two-sided risk options.	This amended section would provide ACOs with more clarity on the expectations and consequences of early termination of a MSSP ACO participation agreement.
§ 425.224(a) (new)	CMS proposes to develop a streamlined process for ACOs that would like to continue participating in the MSSP after the expiration of their current participation agreement. This proposed section would allow current ACOs to request a renewal of their current participation agreement rather than have to submit a new application.	This new section would provide ACOs seeking to continue participation in the MSSP with administrative simplicity.
§ 425.224(b) (new)	CMS proposes to specify the factors CMS will use to determine whether to renew a participation agreement. The factors will include: whether the ACO satisfies criteria for operating under the selected risk model; the ACO's history of compliance; whether the ACO has established that it is in compliance with eligibility and other requirements of the MSSP; whether the ACO met the quality performance standards during at least one of the first two years of the previous agreement; whether an ACO under a two-sided model repaid losses; and the results of a program integrity screening.	This new section would cause ACOs seeking to participate in the MSSP for subsequent agreement periods to pay special attention to compliance criteria as a part of the renewal process because past experience may inform CMS's determinations. It is unclear whether CMS will consider improvements in compliance throughout the agreement period in its evaluation.
§ 425.224(c) (new)	CMS proposes to notify each ACO in writing with the determination of its renewal request. If the renewal is denied, CMS will include the reason and there will be rights to request reconsideration.	The amendment's effects would largely depend on whether CMS adopts the reconsideration review proposals for §§ 425.802 and 804. If so, ACOs would have less room to negotiate with CMS for a renewal of the MSSP agreement.
Subpart D—Program Requirements and Beneficiary Protections		
§ 425.304(d) (delete)	CMS proposes to remove this section that currently addresses how ACOs must maintain information regarding participating TINs and provider/supplier NPIs, as well as how ACOs must update CMS regarding such information.	This amendment to the reporting requirements would be more comprehensively addressed in proposed new § 425.118, as discussed above.
§ 425.306(amended)	CMS proposes to incorporate technical amendments to the ACO participant definition and indicate that each ACO participant that submits claims for primary care services used to determine the ACO's assigned population must be exclusive to one ACO, except those provided by specialists listed in the proposed regulations at Table 3.	This amendment would provide more clarity on CMS's expectations with regard to exclusivity. The effect of these clarifications largely depends on whether CMS adopts the new interpretations of primary care services and the applicable specialties whose delivery of these services affect beneficiary

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		assignment.
§ 425.308(amended)	CMS proposes to impose additional requirements on MSSP ACOs to post information on their publicly available websites, specifically: • key clinical and administrative leaders; • the types of ACO participants or combinations thereof (as listed in § 425.102(a)) forming the ACO; and • the ACO's performance on all quality measures. Such public reports of ACO-specific information on the website would not be subject to marketing review and approval. CMS would be allowed to publicly report ACO-specific information, including but not limited to the information required to be provided by the ACO on its website.	This amendment would subject ACOs to increased transparency and more scrutiny by the general public. ACOs that view their structures as proprietary or sensitive may object to CMS's requirement that they provide information about the types of ACO participants or combinations thereof, and potential ACO participants may view these transparency requirements as problematic.
§ 425.312 (amended)	CMS proposes to clarify that ACO participants must, at the point of care, notify beneficiaries of the ACO provider/suppliers that are participating in the MSSP and the opportunity to opt-out of claims data sharing. To meet these notice requirements, ACOs would be required to post signs in their facilities with required template language notifying beneficiaries of their opt-out rights and participating primary care service providers in the ACO must supply written notices to beneficiaries upon their request. *See also*, § 425.708.	This amendment would reduce ACOs' administrative burden for notification obligations.
§ 425.316 (amended by deleting (c)(3) and (c)(4) and redesignating (c)(5))	CMS proposes to revise § 425.316(c) to clarify CMS's administrative enforcement authority when ACOs fail to meet the quality reporting requirements. CMS wants to remove § 425.316(c)(3) and (4) regarding requests for missing or corrected information, requests for a written explanation for the noncompliance, and termination requests because all of these actions are already authorized under §§ 425.216 and 425.218. The proposed revision to § 425.31(c)(5) replaces "fully and completely" with "accurately, completely, and timely" to emphasize the importance of timely submission of quality measures. *See also* § 425.500(f).	This amendment would reduce ACOs' flexibility to negotiate timelines for quality data submissions.
Subpart E—Assignment of Beneficiaries		
§ 425.400(a) (amended)	CMS proposes the amended § 425.401 criteria as part of the beneficiary assignment process and, in accordance with the revisions to the ACO professional and ACO provider/supplier definitions, clarifies that the only primary care services that would affect beneficiary assignment must be provided "by a physician who is an ACO professional during each benchmarking year and during each performance year." With respect to the proposed new two-sided risk model (Track 3), CMS would add new preliminary provisions at § 425.400(a)(3) stating that Medicare FFS beneficiaries would be prospectively assigned to the ACO at the beginning of each performance year based on the beneficiary's use of primary care services in the most recent 12 months for which data are available (off-set from the calendar year). Such beneficiaries would remain assigned to the ACO at the end of the performance ear unless the exclusion criteria in § 425.401(b) apply.	This amendment would remove the requirement that an ACO professional be an ACO provider/supplier. Thus, CMS is now making it clear that the services furnished by such ACO professional and billed through the TIN of an ACO participant would still be considered for purposes of determining beneficiary assignment to the ACO during the benchmarking period. This would make the reconciliation process even more complex if beneficiaries who previously received services from an ACO professional who ultimately does not participate in the ACO may ultimately receive qualifying primary care services elsewhere. Thus, ACOs will have to pay increased attention to establishing a set of ACO participant TINs with a stable set of beneficiaries to properly estimate assigned beneficiaries.

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§ 425.401 (new)	CMS proposes to clarify the requirements that a Medicare beneficiary must meet before being assigned to an ACO. Specifically, the beneficiary must: • be enrolled in Part A and B for at least one month, with no Part A or Part B-only coverage within the 12-month assignment window; • not have been enrolled in Medicare (group) private health plans within the assignment window; • not be assigned to any other Medicare shared savings initiative; and • reside in the U.S. or U.S. territories and possessions as of the end of the assignment window. The above criteria would serve to exclude beneficiaries who do not meet them in all risk models during the reconciliation process.	These amendments would codify what the agency says is its current assignment methodology that it developed in response to stakeholder and ACO questions about beneficiary assignment eligibility criteria. There still may be errors in assigning beneficiaries, but these criteria may provide more clarity and notice to ACOs on CMS's intent regarding the process. As more beneficiaries enroll in Medicare Advantage or the private plans listed on the health care exchanges, the pool of assignable beneficiaries meeting these criteria would decrease for ACOs. Thus, there may be significant variation between the number of assignable beneficiaries based on benchmarking year data and assignable beneficiaries based on performance year data.
§ 425.402 (amended)	CMS proposes to amend § 425.402(a) to include Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists as ACO professionals whose eligible primary care services would be considered in step 1 of the beneficiary assignment process, and to add new paragraph (b) to identify the physician specialty designations that would be considered in step 2 of the beneficiary assignment process. See Table 2 for the relevant physician specialties. Other amendments to this section incorporate the technical revisions to the "ACO professional" definition and the expanded definition of eligible primary care services in § 425.20. The prospective assignment methodology in this section would also assign beneficiaries to ACOs in Track 3. In addition, the proposal adds § 425.402(c) to provide that when considering services furnished by physicians in Electing Teaching Amendment (ETA) hospitals in the assignment methodology, CMS would use the amount payable under the Physician Fee Schedule for the specified HCPCS code as a proxy for the amount of the allowed charges for the service.	These amendments would likely make it easier for MSSP ACOs to meet the 5,000 assigned beneficiary threshold and more accurately reflect the scope and source of primary care services provided to Medicare beneficiaries. The proposed changes to beneficiary assignment and eligible primary care services would create additional flexibility for certain specialty practitioners to participate in multiple ACOs. CMS is soliciting comments on the use of institutional claims submitted by ETA hospitals for purposes of identifying primary care services furnished by physicians in order to allow these services to be considered in the assignment of beneficiaries to ACOs. CMS's current instructions and process regarding ETA hospital claims for ACOs is in Section 3.5 of the guidance available here.
§ 425.404 (amended)	CMS proposes to continue requiring ACOs that include FQHCs and RHCs to identify, through an attestation, the physicians who provide direct patient primary care services in their ACO participant FQHCs or RHCs, but only for purposes of determining whether a beneficiary is assignable to an ACO. Assignment would account for eligible primary care services provided by "attending provider" physicians identified on the attestations whose NPIs are reported on the claims and the eligible primary care services provided by the "attending provider" non-physician ACO professionals to be added in § 425.402(a) whose NPIs are reported on the claims. All primary care services furnished by non-ACO FQHCs/RHCs would be considered in step 1 of the beneficiary assignment process.	These amendments would, for ACOs including FQHCs and RHCs, reconcile situations where the FQHC/RHC claim is for a primary care service as defined under § 425.20, but the NPI reported on the claim is not the NPI of a physician included in the attestation submitted under § 425.404(a) with these revisions. NOTE: The preamble addresses issues relating to how the assignment methodology applies to claims submitted by Critical Access Hospitals (CAHs) that are ACO participants, but does not propose any regulatory changes. CMS continues to rely in section 3.3 of this guidance with respect to claims submitted under CAH Method II.

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Regulatory Cite in C.F.R. Title 42	Description of the Proposed Amendment	Potential Impact
Subpart G —Shared Savings and Losses		
§ 425.600 (amended, new paragraph (a)(3))	CMS proposes to add § 425.600(a)(3) to create the new two-sided risk model for ACOs (Track 3) and to revise § 425.600(b) to clarify restrictions on whether renewing ACOs may continue under the one-sided risk model (Track 1). Specifically, the only ACOs that may enter a second MSSP agreement period under Track 1 are those ACOs that: were a Track 1 ACO for the first MSSP agreement period; did not generate loses in excess of its negative Minimum Savings Rate in the first 2 performance years of that period; and otherwise meets the renewal criteria under § 425.224(b).	These amendments, and particularly the renewal restrictions, appear to attempt to push more Track 1 ACOs into two-sided risk models, but may still force some Track 1 ACOs (and possibly Track 2 ACOs) to not enter into renewed MSSP agreements with CMS.
§ 425.602(a)(8) (amended)	CMS proposes to clarify that the ACO's benchmark will be adjusted in accordance with the amended § 425.118(b)'s provisions regarding beneficiary assignment.	*See* § 425.118(b) comments.
§ 425.604(d) (amended)	CMS proposes to split this paragraph and allow for Track 1 ACOs in their first MSSP agreement period to share in 50% of the shared savings earned, and Track 1 ACOs in their second MSSP agreement period to share in 40% of the shared savings earned. CMS is soliciting comments on whether subsequent MSSP agreement periods for Track 1 ACOs should result in continuing commensurate 10% reductions in shared savings. Of note, CMS is seeking comments regarding what we can term "split-level" ACOs. This option would be available to Track 1 ACOs that may have some ACO participants that are ready to transition to two-sided risk models and some that desire to remain in Track 1.	This amended section and these renewal restrictions attempt to push more Track 1 ACOs into two-sided risk models, but may still make it unattractive for some Track 1 ACOs to enter into renewed MSSP agreements with CMS. Also, Track 1 ACOs were largely hoping for more than 50% shared savings in these proposed rules. CMS provides a chart showing all of the current and proposed one-sided and two-sided risk models at Table 7.
§ 425.606 (amended)	CMS proposes to change references to the "two-sided risk model" to "Track 2" and establish a Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR) sliding scale ranging between 2% for Track 2 ACOs with large assigned beneficiary populations (over 60,000) to almost 4% for Track 2 ACOs with small assigned beneficiary populations (closer to 5,000). The sliding scale chart is at Table 6.	These revisions would provide a larger risk cushion for Track 2 ACOs with low numbers of assigned beneficiaries. Arguably, there may be less of an incentive to form larger ACOs as a result.
§ 425.610 (new)	CMS proposes to develop and codify details about how it would calculate shared savings and losses for Track 3 ACOs as follows: • a 12-month assignment window offset from the calendar year prior to the start of each performance year, but Part A and Part B expenditures would still be determined based on the calendar year; • a risk adjustment methodology that incorporates HCC prospective risk scores for newly assigned beneficiaries and demographic factors to adjust for changes in the continuously assigned beneficiary population (*see* § 425.20); • the flat 2% MSR/MLR rate currently applicable to Track 2 ACOs; • a maximum 75% shared savings rate, whereby the ACO would be eligible to receive funds up to 20% of its updated benchmark; and • a maximum shared loss rate of 75%, whereby the ACO must repay CMS a minimum of 40% of the losses up to 15% of the updated benchmark.	This section would create a new two-sided risk model with larger shared savings potential that may be attractive to more experienced ACOs. CMS is seeking comment on whether these characteristics are indeed sufficiently attractive.

SUMMARY CHART OF PROPOSED AMENDMENTS TO 42 C.F.R. PART 425 GOVERNING THE MEDICARE SHARED SAVINGS PROGRAM

Regulatory Cite in C.F.R. Title 42	Description of the Proposed Amendment	Potential Impact
Subpart H—Data Sharing with ACOs		
§ 425.702(c)(1) (amended)	CMS proposes to expand the beneficiary identifiable information made available under § 425.702(c)(1) to include the name, date of birth, Health Information Claims Number, and sex for each beneficiary who has a primary care service visit with an ACO participant that bills for primary care services considered during the 12-month assignment period. In addition, CMS proposes to establish minimum data sets of beneficiary identifiable information in operational guidance that would include more data points addressing demographic data such as enrollment status, health status information, utilization rates of Medicare services, and expenditure information related to the use of such services. If CMS adopts the new Track 3 for two-sided risk, the minimum data set would only be made available regarding beneficiaries assigned at the beginning of an ACO's performance year.	This amendment reflects CMS taking a more expansive view of the permissible disclosure of information under HIPAA's definition of "health care operations." As a result, ACOs will have more comprehensive information about their prospectively assigned beneficiaries earlier in their MSSP agreement periods.
§ 425.704 (amended)	CMS proposes to allow ACOs to access (rather than request) beneficiary identifiable claims data at the start of the ACO's agreement period, provided all other requirements for claims data sharing under the MSSP and HIPAA regulations are met, with (1) Track 1 and 2 ACOs participating under Tracks 1 and 2 that request claims data on beneficiaries that are included on their preliminary prospective assigned beneficiary list or those beneficiaries that have received a primary care service from an ACO participant upon whom assignment is based during the most recent 12-month period; or (2) with Track 3 ACOs if the beneficiary's name appears on the prospective assignment list.	This amendment reflects CMS's expanded beneficiary assignment process and potentially gives ACOs more predictability regarding their assigned beneficiary populations. ACOs may also have improved access to the data necessary for health care operations.
§ 425.708 (amended by deleting paragraphs (b) and (c) and shifting (d)-(f) accordingly)	CMS proposes to allow beneficiaries to decline claims data sharing directly through 1-800-MEDICARE rather than through the ACO and to notify beneficiaries of this option through CMS materials such as the "Medicare & You Handbook." Under this proposal, ACOs would no longer have to mail notifications to beneficiaries for them to return to the ACO to decline claims data sharing. Instead, ACOs would be required to post signs in their facilities with template language notifying beneficiaries of their opt-out rights. *See also*, § 425.312.	These amendments would reduce the administrative burden for notification obligations on ACOs.
Subpart I—Reconsideration Review Process		
§ 425.802 (amended)	CMS proposes to reduce all reconsideration requests to "on-the-record" reviews.	This amendment would create a very narrow review process but streamlines the process for CMS. On-the-record reviews would create more pressure for ACOs to address all arguments simultaneously, which may be contrary to CMS's goal to shorten the review process.
§ 425.804 (amended)	CMS proposes to only allow one single exchange of briefs during the "on-the-record" reconsideration review process. There will no longer be opportunities for an oral hearing.	This amendment would create a very narrow review process but streamlines the process for CMS. However, on-the-record reviews would create more pressure for ACOs to address all arguments simultaneously, which may be contrary to CMS's goal to shorten the review process.