BluePeak Advisors is a division of Gallagher Benefit Services, Inc.

Proposed Rule Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

December 27, 2022

On December 27, 2022, the Centers for Medicare & Medicaid Services (CMS) released proposed rule (CMS_FRDOC_0001-3474) in the Federal Register. If finalized, this proposed rule would revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, medication therapy management, marketing and communications, health equity, provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, identification of overpayments, formulary changes, and other programmatic areas. This proposed rule would also codify regulations implementing section 118 of Division CC of the Consolidated Appropriations Act, 2021, section 11404 of the Inflation Reduction Act, and includes a large number of provisions that would codify existing sub-regulatory guidance in the Part C, Part D, and PACE programs. This proposed rule would also amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an identified overpayment.

Comments on the proposed rule are due to CMS on or before February 13, 2022.

An index to the proposed rule, along with highlights of its most significant provisions, is set forth below.

1. Executive Summary (pgs. 1-13)

a. Purpose (pg. 1)

i. Amends regulations for the Medicare Advantage (MA) (Part C), Medicare Cost Plan, and Medicare Prescription Drug Benefit (Part D), and Programs of All-Inclusive Care for the Elderly (PACE)

ii. Amends existing regulations for Medicare Parts A, B, C, and D regarding the standard for identifying overpayment

iii. Implements certain sections of the following:

A. The Inflation Reduction Act (IRA) and 2022

B. The Consolidated Appropriations Act (CAA), 2021

C. The Bipartisan Budget Act (BBA) of 2018

D. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018

b. Summary of Major Provisions (pgs. 1-4)

i. Proposes a health equity index (HEI) award for the 2027 Star Ratings to further incentivize Parts C and D plans to focus on improving care for enrollees with social risk factors (SRFs). This proposal also includes removal of the current reward factor;

ii. Strengthens beneficiary protections and improves MA and Part D marketing by requiring MA organizations and Part D sponsors to disclose specific types of information to enrollees;

iii. Expanding network adequacy requirements to include additional behavioral health specialty types;

iv. Establishes specific enrollee notification requirements for no-cause and for-cause provider contract termination and adding specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur;

v. Proposes changes to the Medication Therapy Management (MTM) to reduce eligibility gaps by requiring plan sponsors to target 10 core chronic diseases identified by CMS: the nine currently included in the program, and adding HIV/AIDS; and lowering the maximum number of covered Part D drugs from eight to five and requiring sponsors to include all Part D maintenance drugs in the targeting criteria; and lowering the methodology for calculating the cost threshold from $4,935 to $1,004;

vi. Updates regulations to specify that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a standing basis in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package service area or accessible format using auxiliary aids and services upon receiving a request for the materials or otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services;

vii. Proposes further clarifications to the application of existing policies with respect to improving health equity, including providing services in a culturally competent manner; codification of "best practices" for organizations to use when developing their provider directories; requires MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees; requires MA organizations to incorporate at least one quality improvement program to reduce disparities in health and health care among enrollees;

viii. Proposes several regulatory changes to address stakeholder concerns about MA organizations' use of prior authorization and its effect on beneficiary access to care;

ix. Proposes to make the Limited Income Newly Eligible Transition (LI NET) program a permanent part of Medicare Part D, as required by the CAA;

x. Amends the existing regulations regarding the standard for "identified overpayment" and align the regulations with statutory language, by removing the existing "reasonable diligence" standard and adopting by reference the False Claims Act definition of "knowing" and "knowingly";

xi. Allows Part D plans to immediately substitute: a new interchangeable biological product for its corresponding reference product, a new unbranded biological product for its corresponding brand name biological product; and a new authorized generic for its corresponding brand name equivalent;

xii. Expands eligibility for the full low-income subsidy (LIS) to individuals with incomes up to 150% of the Federal poverty level (FPL) and higher resource requirements currently applicable to the partial LIS group, per the IRA.

c. Summary of Costs and Benefits (pgs. 5-13)

i. A summary table of the estimated costs of benefits of the various provisions included in the proposed rule may be found in Table 1 on page 5 of the proposed rule.

2. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022 (pgs. 14-28)

a. Applying D-SNP Look-Alike Requirements to Plan Benefit Package Segments (§§ 422.503(e), 422. 504, 422.510 and 422.514) (pg. 14-15)

i. CMS is proposing to close several unanticipated loopholes in the scope of previous regulations adopted for plan years 2021 and 2023 to prohibit D-SNP look-alike plans.

ii. CMS proposes to amend existing regulations at 42 CFR 422.514(d) through (f) to apply to plan segments of MA plans in the same way that the provisions apply to MA plans; as a result, CMS would not contract with or renew a contract with a plan segment where the MA plan or segment is not a D-SNP.

A. Applying D-SNP look-alike contracting limitations only at the MA plan level without applying it to plan segments creates a loophole through which D-SNP look-alikes could persist, contrary to the stated objectives in prior rulemaking.

B. CMS identified 47 non-SNP MA plans that meet regulatory criteria using January 2022 data; applying the same criteria at the segment level would have identified three additional non-SNP MA plans as D-SNP look-alikes; collectively those plans have approximately 3,000 enrollees.

C. This proposed change would allow CMS to sever a segment from an MA plan and allow the remaining segments of that MA plan to continue along with any other MA plans offered under the same contract.

D. CMS also proposes to amend existing regulations to adopt a new contract term that MA organizations agree not to segment an MA plan in a way that results in the D-SNP look-alike; these amendments would allow CMS to eliminate existing D-SNP look-alike segments, as well as prevent new D-SNP look-alikes.

iii. CMS is proposing to amend 42 CFR 422.514(d)(1) to apply it to both new and existing (or renewing) MA plans that are not D-SNPs and submit bids with projected enrollment of 80% or more enrollees of the plan's total enrollment that are dually eligible for Medicare and Medicaid.

A. Pending finalization of this proposal, CMS will continue to prohibit contracts with new MA plans that meet the criteria; the earliest the proposed revision to expand the scope can apply is 2024.

iv. CMS proposed to amend 42 CFR 422.510(a)(4), to add language that permits CMS to terminate an MA contract when the MA organization meet the criteria in 42 CFR 422.514(d)(1) or (d)(2).

A. The agency believes that it already has sufficient authority for termination of contracts under this circumstance but believed that adopting specific language will avoid any inadvertent ambiguity on the topic.

b. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes

(§ 423.38) (pgs. 15-16)

i. Based on Medicare enrollment statutory changes made by the CAA, CMS is proposing to revise the start and end date for the special enrollment period (SEP) for Part D for individuals who enroll in Part B during the Part B General Enrollment Period (GEP).

ii. Under the modification, starting January 1, 2023, an individual who is not entitled to premium-free Part A, and who enrolls in Part B during the GEP is eligible to use the Part D SEP to request enrollment in a Part D plan; this SEP will begin when the individual applies for Part B and will continue through the first two months of enrollment in Part B.

iii. Where an individual uses this Part D SEP to request enrollment in a Part D plan, the Part D plan enrollment would be effective the first of the month following the month the part D plan sponsor receives the enrollment request.

iv. An individual's Part D enrollment effective date cannot be prior to the Part A/Part B entitlement date, and the individual must also meet other Part D plan eligibility criteria; the Social Security Administration (SSA) will have to first process the individual's Part B application and populate the CMS enrollment systems for a Part D plan to have access to the entitlement information.

c. Alignment of Part C and Part D Special Enrollment Periods with Medicare Exceptional Condition Enrollment (§§ 422.62 and 423.38) (pgs. 16-18)

i. CMS is proposing to add corresponding exceptional condition SEPs for MA and Part D enrollment that align with the new Medicare premium Part A and B exceptional condition SEPs that CMS previously finalized in 42 CFR 406.27 and 407.23.

ii. Under the proposal, individuals who use an exceptional condition SEP to enroll in premium Part A and/or Part B will be provided an opportunity to enroll in a MA or Part D plan, provided that the individual meets applicable eligibility requirements for the plan.

iii. The SEP would begin when the individual submits the application for premium Part A and Part B, or only Part B, and would continue for the first two months of enrollment in Part A (premium or premium-free) and Part B. Enrollment would be effective the first of the month following the month the MA or Part D plan receives the enrollment request.

d. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program (§§ 423.2500 through 423.2536) (pgs. 18-27)

i. CMS established the LI NET program as a demonstration in 2010 to consolidate the administration of transitional and retroactive Part D coverage for eligible beneficiaries to a single Part D sponsor.

ii. The LI NET demonstration provides point-of-sale coverage for beneficiaries who demonstrate an immediate need for prescriptions, and also provides retroactive and/or temporary coverage for beneficiaries determined to be eligible, or likely to be eligible, for the Part D LIS.

iii. The CAA requires CMS to "carry out a program to provide transitional coverage for covered Part D drugs for LI NET eligible individuals" no later than January 1, 2024 and makes the LI NET a permanent program within Part D beginning in 2024.

iv. CMS is proposing to codify the existing LI NET demonstration into a permanent program, including the appointment of a Part D sponsor to serve as the LI NET sponsor.

e. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program

(§§ 423.773 and 423.780) (pgs. 27-28)

i. The IRA expanded eligibility for the full LIS subsidy group to individuals with incomes below 150% of the FPL (up from 135%) and who meet the resource limits for the existing partial subsidy program ($14,010 for a single beneficiary in 2022 and $27,950 for married beneficiaries in 2022).

ii. CMS is proposing changes to align existing regulations with the statutory text, effective January 1, 2024.

3. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (pgs. 28-109)

a. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152) (pgs. 28-37)

i. Current Medicare regulations require MA plans that offer coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

ii. CMS is proposing the following amendments to existing regulations with an intention to clarify the scope of the existing requirements, consistent with the direction and goals of President Biden's recent Executive Order on health equity (E.O. 13985):

A. Revise the current paragraph heading at 42 CFR 422.112(a)(8) from "Cultural Considerations" to read "Ensuring Equitable Access to Medicare Advantage (MA) Services" to reflect the inclusive nature of the protections more clearly.

B. Amend the regulatory test to identify additional types of underserved groups to provide clarity with regard to the populations MA organizations must accommodate in order to meet requirements for access to services: people with limited English proficiency or reading skills; people of ethnic, cultural, racial, or religious minorities; people with disabilities; people who identify as lesbian, gay, bisexual, or other diverse sexual orientations; people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; people who live in rural areas and other areas with high levels of deprivation; and people otherwise adversely affected by persistent poverty or inequality.

C. Add two new requirements to MA organization provider directories: the MA organization must include providers' cultural and linguistic capabilities (including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office) and identify certain providers waived to treat patients with medications for opioid use disorder (MOUD).

D. Add requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist them with accessing any medically necessary covered telehealth benefits.

E. Require MA organizations to incorporate one or more activities into their overall quality improvement (QI) program that reduce disparities in health and health care among their enrollees.

b. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116) (pgs. 37-42)

i. CMS is proposing to add to the following specialties to the list of provider specialties

subject to network adequacy evaluations: clinical psychology, clinical social work, and Prescribers of Medication for Opioid Use Disorder (providers with a waiver under section 303(g)(2) of the Controlled Substances Act and Opioid Treatment Programs).

A. CMS also proposes to amend the list of health care providers in the existing access to services standards at 42 CFR 422.112(a)(1)(i) to include that the network must also include providers that specialize in behavioral health services.

B. Under the proposal, MA plans may receive a 10-percentage point credit towards percentage of beneficiaries that reside within published time and distance standards when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits.

ii. CMS is proposing to add behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services.

A. Additionally, under the proposal, MA plans would be required to treat a mental health emergency as an emergency medical condition, under which the use of prior authorization would be prohibited.

iii. CMS is also proposing to codify appointment wait times as standards for primary care services and extend those standards to behavioral health services. CMS is seeking comment on alternative specific appointment wait times standards to apply to MA organizations.

c. Medicare Advantage (MA) Network Adequacy: Access to Services (§ 422.112) (pgs. 42-43)

i. CMS is proposing to amend current regulations to align more closely with current sub regulatory policy and formally require MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

ii. If finalized, CMS intends to continue account management activity, complaint tracking and reporting, and auditing activities to ensure MA organizations' compliance with the proposed regulation.

d. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267) (pgs. 43-46)

i. Current regulations require notification to MA enrollees when a provider network participation contract terminates, with a good faith effort to provide written notice at least 30 calendar days prior to the termination for all enrollees who are patients seen on a regular basis by the provider. When the provider is a primary care provider, all enrollees who are patients must be notified.

ii. CMS is proposing to limit the "good faith effort" standard for no-cause provider contract terminations, since those require a minimum of 60-day notice to provider; this notice requirement means that MA organizations should have no problem meeting the 30-day minimum standard for no-cause terminations.

iii. Proposes § 422.2267(e)(12)(ii)(D), that the provider termination notice must provide information about the Annual Coordinated Election Period (AEP) and the MA Open Enrollment Period (MA-OEP) and must explain that an enrollee who is impacted by the provider termination may contact 1-800-MEDICARE to request assistance in identifying

and switching to other coverage, or to request consideration for a special election period (SEP), as specified in § 422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP

iv. CMS is also proposing to add specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur.

A. Behavioral health providers would be added to the current primary care provider notification requirements (meaning that all enrollees who have seen the provider must be notified).

B. MA organizations would have to provide a minimum of 45 calendar day notice before termination effective date.

C. MA organizations would have to send both written and telephonic notice of the termination to the enrollee that involve a primary care or behavioral health provider; MA organizations would be required to continue attempting to reach the beneficiary via telephone and CMS is soliciting comments on how many attempts should be required.

D. Notification timelines for all other specialties would remain at 30 days.

v. CMS is proposing to codify the existing sub regulatory guidance regarding the content of provider termination notices that has been in effect since 2016.

e. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138) (pgs. 46-57)

i. CMS is proposing policies that would provide less flexibility for MA organizations to deny or limit coverage of basic benefits:

A. CMS is proposing to clarify that MA organizations must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, when making coverage decisions (e.g., the statutory exemption for the 3-day qualifying hospital stay for coverage of skilled nursing facility services).

B. When an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies.

C. This proposal would not impact the regulation allowing MA plans to use step therapy policies for Part B drugs under certain circumstances.

D. When coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. An MA organizations' internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature.

ii. MA organizations must make medical necessity determinations based on coverage and benefit criteria and may not deny coverage for basic benefits based on coverage criteria not found in regulatory sources. MA organizations must also consider the enrollee's

medical history, physician recommendations, and clinical notes and involve the MA organization's medical directors in all organizational determinations and reconsiderations of medical necessity.

iii. CMS is proposing to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary based on regulatory standards, or to ensure that the furnishing of supplemental benefits is clinically appropriate.

   A. Additionally, if the plan approved the furnishing of a service through an advanced determination of coverage, it may not later deny coverage on the basis of a lack of medical necessity (except those for which the plan has good cause for fraud or similar fault).

   B. Prior authorization policies are also considered part of the plan benefit design, and therefore cannot be used to discriminate or direct enrollees away from certain types of services.

iv. MA plans must also ensure continuity of care by establishing policies for using prior authorization for basic benefits that are valid for the duration of the entire approved prescribed or ordered course of treatment or service.

v. MA organizations must also provide for a minimum 90-day transition period for any ongoing course of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the treatment was commenced with an out-of-network provider. The MA organization must not disrupt or require authorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

vi. CMS notes that the proposals provide minimum standards for an acceptable benefit design for the agency to apply in reviewing and evaluating bids, in addition to establishing important protections to ensure that enrollees have access to medically necessary items and services covered under Part A and Part B.

vii. CMS is proposing to require MA organizations to establish a Utilization Management (UM) committee to operate like a Pharmacy and Therapeutics (P&T) committee. Any MA organization that uses UM policies, such as prior authorization, would be required to use such a committee that is led by an MA plan's medical director.

viii. Starting January 1, 2024, MA plans would only be able to use UM policies reviewed and approved for use by the committee. The committee would then have to review the policies annually for all UM used by the MA plan.

   A. Proposed committee membership and documentation requirements are modeled after the longstanding Part D P&T committee requirements.

   B. CMS is seeking comment on whether MA plans should be permitted to utilize the proposed UM committee to also meet P&T committee requirements.

ix. CMS is soliciting comments in response to complaints alleging that MA organizations are increasingly terminating beneficiaries' coverage of post-acute care before the beneficiaries are healthy enough to return home; to address, CMS is proposing to revoke the existing policy that when a health care service can be Medicare-covered and delivered in more than one way, the MA plan could choose how the covered services will be provided. Under the proposed revision, when care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for a MA enrollee, the MA organization

may only deny coverage of the service or setting on the basis of the ordered services failing to meet coverage criteria.

x. CMS continues to encourage MA plans to adopt "gold-carding" programs that relax or eliminate prior authorization requirements for providers who have demonstrated compliance with plan requirements.

xi. CMS is also requiring MA organizations to review PA procedures, protocols, and systems to identify and address vulnerabilities that can lead to errors.

f. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V) (pgs. 57-58)

i. CMS is soliciting comments on a potential revision to the MA Reward and Incentive programs. Under the option, MA plans may uniformly offer enrollees rewards in exchange for participating in health-related activities which either promote improved health, prevent injury and illness, or promote efficient use of health care resources.

ii. Under current policy, the programs may not offer cash or "cash equivalents" (such as a check or general-purpose debit card), but they may offer a gift card that may only be redeemed at specific retailers or for a specific category of items or services.

iii. The final rule implementing the rewards program does not specifically address gift cards from big-box stores or Amazon in relation to the prohibition on "cash equivalents" and CMS is soliciting comment on whether the "cash equivalent" definition requires further defining.

g. Section 1876 Cost Contract Plans and Cost-Sharing for the COVID-19 Vaccine and its Administration (§ 417.454) (pg. 58)

i. CMS is proposing to require cost contract plans to cover COVID-19 vaccines and their administration with $0 cost sharing in-network.

h. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629) (pgs. 58-60)

i. CMS is proposing to add to existing requirements for review of medical necessity decisions, that the physician or other appropriate health care professional who conducts the review must have expertise in the field of medicine that is appropriate for the item or service being requested.

ii. If the proposal is finalized, CMS expects MA organizations to apply the standard of "expertise appropriate for the specific service at issue" at the organization determination level in the same manner as plans have applied this standard at the reconsideration level.

iii. The requirement only applied when the MA organization expects to issue a partially or fully adverse medical necessity decision and does not limit the scope of reviewers where the plan approves coverage or determines that an item or service is medically necessary.

i. Effect of Change of Ownership Without Novation Agreement (§§ 422.550 and 423.551) (pgs. 60-61)

i. In the event of a change of ownership involving a MA organization or Part D plan, advance notice must be provided to CMS and the parties to the transaction must enter into a written novation agreement that meets CMS' requirements.

ii. Current regulations do not fully address what happens when the contract becomes "invalid" due to a change in ownership without a novation agreement and/or notice to CMS (i.e., what happens to the existing CMS contract that was held by an entity that was sold).

iii. CMS is proposing to revise current regulations to make it clear that the affected contract may be unilaterally terminated by CMS. Additionally, contracts may be unilaterally terminated by CMS for failure to comply with the written novation agreement requirements.

iv. CMS is also proposing to amend the regulations to outline the process the agency would follow, including imposing applicable sanctions before terminating a contract that has a change in ownership without a novation agreement.

j. Civil Money Penalty Methodology (§§ 422.760 and 423.760) (pgs. 61)

i. In 2021, CMS finalized a policy to update the minimum Civil Monetary Penalty (CMP) amounts no more often than every three years. In hindsight, the agency believes that other parts of the regulations unnecessarily complicated CMS's approach to calculating CMPs, which has the effect of limiting CMS's ability to protect beneficiaries when CMS determines that an organization's non-compliance warrants a CMP amount that is higher than would normally be applied using CMP methodology.

ii. CMS is proposing to revise and add new provisions, which will set standard minimum penalty amounts and aggravating factor amounts for per-determination and per-enrollee penalties on an annual basis.

iii. CMS will also use discretion to issue penalties up to the maximum amount when it is determined that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts.

k. Call Center Interpreter Standards (§§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A)) (pgs. 61-63)

i. Building on previous regulatory proposals to establish and strengthen MA and Part D enrollee access to plan interpreter services, CMS is proposing to codify requirements for minimum qualifications for interpreters available to non-English speaking and Limited English Proficiency (LEP) individuals at MA and Part D call centers.

ii. Under the proposal, MA organizations and Part D sponsors must use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

l. Call Center Teletypewriter (TTY) Services (§§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B)) (pg. 63)

i. When an MA organization or Part D sponsor operates their own TTY device and thereby creates a direct TTY to TTY communication, the plan customer is also the TTY operator. However, where MA organizations and Part D sponsors utilize telecommunication relay systems, a TTY operator serves as an intermediary between the caller and the plan's customer service representative and is not able to answer the caller's questions about plan benefits.

ii. CMS is proposing to make a technical change to remove any ambiguity that might result

from the use of the term "TTY operator". CMS is proposing to modify existing regulations to require that the plan's call center establish contact with a customer service representative within seven minutes on no fewer than 80 percent of incoming calls requiring TTY services.

m. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294) (pgs. 63-68)

i. CMS is proposing to prohibit changes to non-drug benefits, premiums, and cost sharing by an MA organization starting after plans are permitted to being marketing prospective contract year offerings on October 1 for the following contract year and until the end of the applicable contract year.

A. Similarly, CMS is proposing to codify into regulations longstanding Part D program policy prohibiting sponsors from similar changes to formularies, bid-level cost-sharing, or cost-sharing for some or all of a plan's enrollees during the same timeframe.

ii. Failure to Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts:

A. CMS is proposing to require Part D sponsors to:

1. Refund incorrect collections of premiums and cost-sharing; and

2. Recover underpayments of premiums and cost-sharing.

iii. CMS is proposing a lookback period of three years and timeframe of 45 days to complete overpayments and underpayment notices, as well as a *de minimis* threshold ($2) for such refunds and recoveries and is soliciting comments regarding the addition of similar requirements in MA.

n. Clarify Language Related to Submission of a Valid Application (§§ 422.502 and 423.503) (pgs. 68-70)

i. CMS is proposing to codify existing authority to decline to consider a substantially incomplete application for a new or expanded Part C or D contract. The proposal also includes codified criteria for determining when an application is "substantially incomplete."

ii. This policy had been in place since a final rule released in April 2011, in which CMS noted that to meet the application submission deadline, some entities had submitted applications that were so lacking in required information as to fail to constitute a valid submission. These "placeholder" applications would allow entities more time to submit complete applications than applicants that had submitted complete applications by the deadline.

A. In the preamble to the April 2011 rule, CMS discussed that this was considered an abuse of the application review process and have therefore treated such substantially incomplete applications as invalid since the enactment of the April 2011 final rule.

o. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267) (pgs. 70-73)

i. Under the proposal, MA organizations and Part D sponsors would be required to provide materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5% of the individuals in a plan benefit package service area or is

accessible using auxiliary aids and services.

ii. Once a plan learns of an enrollee's preferred language and/or need for auxiliary aids and services, the plan must provide required materials in that language and/or format as long as the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide required materials in a different manner.

A. This requirement also applies to individualized plans of care for SNP enrollees.

iii. These requirements are in addition to requirements related to providing meaningful access to individuals with limited English proficiency and effective communication for individuals with disabilities. Where one set of regulations imposes a higher or different standard, but it is not impossible for the plan to comply with both, the plan must comply with both. These requirements also apply to cost plans.

iv. CMS is also proposing to apply the same translation standards for D-SNPs to FIDE SNPs and HIDE SNPs, though a State may impose a higher or more stringent translation requirement on its Medicaid managed care contract.

p. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423) (pgs. 73-85)

i. CMS has statutory authority to review marketing materials, develop marketing standards, and ensure that marketing materials are accurate and not misleading. CMS also has authority to prohibit certain marketing activities and add additional standards to the MA program that the Secretary determines are necessary for CMS to carry out the program. Using these authorities, CMS is proposing the following changes to existing regulations:

A. Requiring third parties to submit marketing materials;

B. Notifying enrollees annually that they can opt out of plan business calls;

C. Limit the ability of plans and agents to contract prospective enrollees beyond six months from the time they submit a Scope of Appointment (SOA) or Business Reply Card (BRC);

D. Requiring website provider directories to be searchable by all required elements (e.g., name, phone number, address);

E. Adding "effect on current coverage" to the pre-enrollment checklist during an enrollment call;

F. Requiring plans to list benefits at the beginning of the Summary of Benefits and in a specified order;

G. Labeling the non-renewal notice as standardized rather than a model, consistent with CMS' guidance instructions;

H. Limiting the requirements to record calls between third-party marketing organizations (TPMPs) and beneficiaries to marketing and enrollment calls;

I. Clarifying that the prohibition on door-to-door contact without a prior appointment still applies after collection of a BRC or SOA;

J. Prohibiting marketing of benefits in a service area where the benefits are not available;

K. Prohibiting marketing based on information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured

individuals, costs that dually eligible beneficiaries are not responsible to pay, or other unrealized costs of a Medicare beneficiary;

L. Requiring TPMOs to list or mention all of the MA organization or Part D sponsors that they sell;

M. Requiring MA organizations and Part D sponsors to have an oversight plan that monitors agent/broker activities and reports agent/broker non-compliance to CMS;

N. Modifying the TPMO disclaimer to add State Health Insurance Programs (SHIPs) as an option for beneficiaries to obtain additional help;

O. Placing discrete limits on the use of the Medicare name, logo, and Medicare card;

P. Prohibiting the use of superlatives (e.g., "best" or "most") in marketing unless the materials provides documentation to support the statement, and the documentation is for the current or prior year; and

Q. Clarifying the requirement to record calls between TPMOs and beneficiaries such that it is clear that the requirement includes virtual connections such as Zoom and Facetime.

q. Changes to an Approved Formulary (§§ 423.4, 423.100, 423.104, 423.120, and 423.128) (pgs. 85-91)

i. The agency is proposing to codify longstanding sub-regulatory guidance and terminology (such as classification of changes as either "maintenance" or "non-maintenance") that specify when and how Part D sponsors obtain approval to make negative formulary changes and the enrollees to whom those changes would apply. In addition, updates the enrollee notice requirements for these changes to align with current policy.

ii. CMS is also proposing a new category of negative formulary changes called "immediate negative formulary changes." Currently, plan sponsors are exempt from transition fill requirements when making immediate generic substitutions. CMS is proposing to exempt Part D sponsors making any immediate negative formulary changes (for all types of immediate substitutions and also market withdrawals) from providing transition supplies. Plan sponsors would also be able to make immediate negative formulary changes at any time in the year. and exempt these changes from the negative change request and approval process.

iii. CMS is also proposing to expand the definition of immediate negative formulary changes to include: substitute a new interchangeable biological product for its corresponding reference product; a new unbranded biological product for its corresponding brand-name biological product; or a new authorized generic for its corresponding brand-name alternative.

r. Part D Medication Therapy Management (MTM) Program (§ 423.153(d)) (pgs. 91-97)

i. CMS is proposing the following modifications to the MTM program:

A. Codify the current nine core chronic diseases in regulation and add HIV/AIDS as a core chronic disease, for a total of 10 core chronic diseases and require plan sponsors to include all 10 core chronic diseases in their targeting criteria;

B. Reduce the maximum number of covered Part D drugs a sponsor may require for MTM eligibility from eight drugs to five drugs;

C. Require plan sponsors to include all Part D maintenance drugs when determining

the number of drugs an enrollee is taking for purposes of MTM eligibility; and

D. Lower the annual cost threshold ($4,935 in 2023) to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020).

ii. CMS is proposing these changes because the eligibility criteria established early in the Part D program were identified based on a targeted program size; the proposed changes would focus on Part D drug utilization and beneficiaries with complex patient profiles and drug regimens, with less emphasis on high drug costs. The proposed changes also better align MTM eligibility criteria with the statutory goals of reducing the risk of adverse events, including adverse drug interactions, and optimizing therapeutic outcomes for beneficiaries with multiple chronic conditions and who take multiple Part D drugs, while maintaining a reasonable cost criterion.

iii. CMS is proposing to amend current regulations to specify that for the comprehensive medication review (CMR) to be performed with an individual other than the beneficiary, the beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment. This flexibility would not apply to situations where the sponsor is unable to reach the beneficiary, if there is no evidence of cognitive impairment, or the beneficiary declines the CMR offer.

A. CMS is also proposing to amend existing regulatory text to require that CMR be performed either in-person or via synchronous telehealth to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth.

s. Standards for Electronic Prescribing (§ 423.160) (pgs. 97-101)

i. CMS is proposing a joint approach to adopting and updating electronic prescribing standards in order to mitigate potential compliance challenges for HHS and the healthcare industry that may result from independent adoption of such standards:

A. After a transition period (July 1, 2023 – December 31, 2024), requiring the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2022011 proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for transmitting prescriptions and prescription-related information (including medication history and electronic prior authorization);

B. Starting January 1, 2025, requiring the NCPDP Real-Time Prescription Benefit (RTPB) standard version 12 proposed for adoption at 45 CFR 170.205(c) as the standard for prescriber real-time benefit tools supported by Part D sponsors; and

C. Revising current regulatory text referring to standards for eligibility transactions by adding a new paragraph indicating that eligibility transactions must utilize the applicable standard names in the HIPAA regulation at 45 CFR 162.1202, starting July 1, 2023.

t. Adoption of Health IT Standards (45 CFR 170.205) (pgs. 101-105)

i. The Office of the National Coordinator (ONC) proposes to adopt standards for electronic prescribing and related activities on behalf of HHS as part of a nationwide health information technology infrastructure that supports reducing burden and health care costs and improving patient care.

A. ONC proposes to adopt the following implementation specifications at 45 CFR 170.205(b)(2) and (c), on behalf of the Secretary:

1. NCPDP SCRIPT Standard, Implementation Guide, Version 2022011
2. NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12, Electronic Prescribing

B. ONC is proposing to remove NCPDP SCRIPT standard version 10.6 from 45 CFR 170.205(b)(2) and adopt NCPDP SCRIPT standard version 2022011 in 45 CFR 170.205(b)(2).

1. ONC is proposing to revise 45 CFR 170.205(b)(1) that adoption of NCPDP SCRIPT standard version 2017071 will expire January 1, 2025. CMS is requesting comment on extending the transition period for an additional year.

ii. While CMS and ONC have worked closely together to ensure consistent adoption of standards through regulatory actions, the current practice of different HHS agencies conducting parallel adoption of the same standards may result in additional regulatory burden and confusion for stakeholders.

iii. Under this proposed approach, HHS would adopt standards specified (e.g., the NCPDP SCRIPT standard version 2022011 and the NCPDP Real-Time Prescription Benefit standard version 12) under the Secretary's authority to adopt health IT standards in the Public Health Service Act (PHSA).

iv. If finalized, these proposals would result in the addition and incorporation by reference to the proposed standards in a single Code of Federal Regulations location of 45 CFR 170.205. Programs across HHS would then cross-reference these adopted standards.

v. This proposal would only pertain to the adoption and incorporation by reference of the proposed standards, and when these standards are available for use by HHS. CMS and ONC would continue to set other program requirements independently for programs such as the ONC Health IT Certification Program and the Part D program, which may include additional amendments or guidance related to the use of standards specific to each program.

u. Incorporation by Reference (45 CFR 170.299) (pgs. 105-106)

i. The Office of the Federal Register has established requirements for materials that agencies propose to incorporate by reference in the Code of Federal Regulations.

ii. CMS is providing the following summaries of the standards proposed for adoption:

A. NCPDP SCRIPT Standard Implementation Guide, Version 2022011, January 2022: URL: http://www.ncpdp.org/Standards/Standards-Info. Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

B. NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 12, October 2021: URL: http://www.ncpdp.org/Standards/Standards-Info. Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

C. As an alternative, a copy of the standards may be_viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology.

v. Limitation on PDP Contracts Held by Subsidiaries of the Same Parent (§ 423.272) (pgs.

106-108)

i. CMS is proposing to limit the number of PDP contracts under which a Part D sponsor or its parent organization, directly or through subsidiaries, can offer individual market PBPs in a PDP region to one contract per region.

ii. Parent organizations that do not currently meet this requirement or that violate the requirement following a future acquisition would be granted a two-year transition period to come into compliance.

iii. This is a continuation of longstanding CMS policy to encourage meaningful competition among and a level playing field for Part D sponsors in the Part D program, including previous policies to limit to three per region on the number of plan benefit packages (PBPs) that a sponsor can offer, the requirement that PDP PBPs offered by a sponsor be "substantially different," and the prohibition on approval of application that would result in a sponsor of its parent holding more than one PDP contract per region.

w. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 422.326(c), 423.360(c), (§ 401.305(a)(2)) (pgs. 108-109)

i. In response to relevant litigation challenging previous final rules, CMS is proposing the following changes to overpayment rules:

A. Medicare Part A and Part B: remove the existing standard at 42 CFR 401.305(a)(2) and adopt, by reference, the False Claims Act definition of "knowing" and "knowingly." Under the proposed change, a provider or supplier has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

B. Medicare Advantage and Part D: amend 42 CFR 422.326(c) and 423.360(c) to change the standard for "identified overpayment" to align with the statutory obligation provided by Congress in section 1128J(d)(4)(A) of the Social Security Act, which provides that the terms "knowing" and "knowingly" have the meaning given those terms in the False Claims Act at 31 U.S.C. 3729(b)(1)(A). CMS proposes to adopt, by reference, the False Claims Act definition of "knowing" and "knowingly." Under the proposed rule, an MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

4. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies (pgs. 109-162)

a. Amending the Definition of Severe or Disabling Chronic Condition; Defining C-SNPs and Plan Types; and Codifying List of Chronic Conditions (§ 422.2) (pgs. 109-115)

i. The BBA revised the definition of "severe or disabling chronic condition" for purposes of identifying individuals eligible to enroll in Chronic Care Special Needs Plans (C-SNPs) beginning January 1, 2022; added care management requirements for special needs individuals who have a severe or disabling chronic condition; directed the Secretary to convene a panel of clinical advisors to establish and update a list of severe or disabling chronic conditions that meet certain criteria; mandated the inclusion of several current C-SNP chronic conditions onto the list; and directed that the panel take into account the availability of benefits in the Medicare Advantage Value-Based Insurance Design model.

ii. CMS is proposing to codify the BBA's amendment of the definition of severe or disabling chronic condition. Under the new definition, an eligible individual must, on or after

January 1, 2022, “have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination.”

iii. The statute further requires the Secretary to convene a panel of clinical advisors every five years to review and revise a list of chronic conditions that meet two sets of criteria:

A. The amended definition of a severe or disabling chronic condition as outlined in the BBA; and

B. Conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a specialized MA plan for special needs individuals and either (1) as a result of enrollment in a C-SNP, the enrollee with the condition would have a reasonable expectation of meeting a certain standard regarding health status, outcomes and costs compared to other coverage options, or (2) the condition has a low prevalence in the general population of Medicare beneficiaries or a disproportionally high per-beneficiary cost.

iv. In 2019, the SNP Chronic Condition Panel met and identified 22 chronic conditions as meeting the statutory criteria. CMS is proposing to codify the list of chronic conditions created by the panel. The complete list is located on page 115 of the proposed rule.

v. The panel recommended the creation of several new chronic condition categories that differ from how the current list. By including these categories, CMS is proposing that C-SNPs will be able to create benefit packages and care coordination services to address the needs of beneficiaries who share the same functional needs even if their specific disease or chronic condition may differ.

vi. This new definition of severe or disabling chronic condition will be applicable for plan years beginning on or after January 1, 2025.

vii. With respect to the definition of C-SNP and the description of special needs plans, CMS is proposing to codify current guidance regarding the ability of MA organizations to offer a C-SNP that focuses on single or multiple chronic conditions. CMS currently allows MA Organizations to apply to offer a C-SNP that includes specific combinations of CMS-approved groups of commonly co-morbid and clinically linked conditions and is proposing to codify this current list of combinations. Enrollees need only have one of the qualifying conditions for enrollment when a C-SNP focuses on multiple conditions:

A. Diabetes mellitus and chronic heart failure;

B. Chronic heart failure and cardiovascular disorders;

C. Diabetes mellitus and cardiovascular disorders;

D. Diabetes mellitus, chronic heart failure, and cardiovascular disorders; and

E. Stroke and cardiovascular disorders.

viii. CMS is also proposing to add the following three additional groupings:

A. Anxiety associated with COPD;

B. CKD and post-renal organ transplantation; and

C. Substance Use Disorder (SUD) and Chronic and disabling mental health conditions.

b. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2) al Activity (pgs. 115-118)

i. CMS is proposing to add the following:

A. A definition of institutional special needs plans (I-SNPs) and three additional definitions for each of the current I-SNP types that uses the term "specialized MA plan for special needs individuals" and therefore incorporates the requirements and limitations on SNPs that are included in that definition in 42 CFR 422.2. CMS is also proposing to include in the definition the following types: I-SNP Institutionalized, I-SNP Equivalent, and I-SNP Hybrid.

1. I-SNP types that enroll only Medicare beneficiaries who meet the definition of "institutionalized" would be called "Facility-based Institutional Special Needs Plans" (FI-SNP).

2. I-SNP types that restrict enrollment to MA eligible individuals who meet the definition of "institutionalized-equivalent" would be called "Institutional-Equivalent Special Needs Plan" (IE-SNP).

3. I-SNP types that restrict enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent would be called "Hybrid Institutional Special Needs Plan" (HI-SNP).

B. Codify, as part of the definitions for I-SNPs that enroll special needs individuals who are institutionalized, current policies that address a number of requirements that the contract between the I-SNP and the long-term care (LTC) facility must include in order for an I-SNP to meet CMS compliance, including requirements allowing I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized.

c. Definition of Network-Based Plan (§§ 422.2 and 422.114) (pgs. 118-119)

i. This proposed revision would move the current definition of a network-based plan from 42 CFR 422.114(a)(3)(ii) to the definitions section in 422.2. This proposed change has no implications for other provisions in part 422 in which the definition or description of network plans play a role.

d. Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74) (pg. 119)

i. Current sub regulatory guidance specifically provides that plans send certain notices prior to and following the effective date of involuntary disenrollment based on loss of special needs status. Providing these members at least 30 days advance notice of disenrollment, along with information about deemed continued eligibility for an SEP to elect other coverage, gives beneficiaries ample time to prove they are still eligible for their SNP or to evaluate other coverage options.

ii. CMS is proposing to codify current policy for MA plan notices prior to a member's disenrollment for loss of special needs status, as well as a final disenrollment notice. The plan would be required to provide a minimum of 30 days advance notice of disenrollment, regardless of the date of the loss of special needs status. The advance notice would be provided within 10 calendar days of learning of the loss of special needs status. The plan would also need to provide a final disenrollment notice within three business days following the disenrollment effective date.

e. Involuntary Disenrollment for Individuals Enrolled in a MA Medical Savings Account (MSA) Plan (§ 422.74) (pgs. 119-120)

i. Restrictions on enrollment in a MA MSA plan are established via regulations. The current regulations do not specify whether the eligibility criteria, which preclude an individual with certain health care coverage from electing an MA MSA plan, are applicable to individuals who gain or become eligible for other coverage while enrolled in an MA MSA plan. CMS has historically understood the eligibility criteria to mean that an enrollee in an MSA plan is not able to remain a member of the MSA plan and must be disenrolled by the plan when the individual ceases to meet the statutory and regulatory criteria for eligibility.

ii. CMS is proposing to amend current language to require that an MA MSA enrollee must be disenrolled, prospectively, due to the loss of eligibility. If an MA MSA enrollee does not provide assurances that he or she will reside in the US for at least 183 days during the year the election is effective, is eligible for or begin receiving health benefits through Medicaid, FEHBP, DoD, or the VA or obtains other health coverage that covered all or part of the annual Medicare MSA deductible, that enrollee must be involuntarily disenrolled by the MSA plan effective the first day of the calendar month after the month in which notice by the MA organization is issued that the individual no longer meets the MA MSA's eligibility criteria.

f. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (§ 422.101) (pgs. 120-125)

i. CMS is proposing to amend current regulations to add the minimum overall score requirement for approval of a SNP's Model of Care (MOC), using the term "aggregate minimum benchmark." CMS is proposing to use the same minimum standard for the aggregate minimum benchmark as is currently used by NCQA in reviewing and approving MOCs.

A. CMS is also proposing to codify the current practice that, in addition to the current requirement that all SNPs must meet a minimum benchmark score of 50% on each element, each SNP's MOC must meet an aggregate minimum benchmark of 70%.

B. C-SNP MOCs are annually reviewed and evaluated and are only eligible to receive a MOC approval for one year.

C. CMS proposes to apply the following annual review requirements to the MOCs of all D-SNPs and I-SNPs:

1. A MOC that receives an aggregate minimum benchmark of 85% or greater is approved for three years;

2. A MOC that received a score of 75%-84% is approved for two years; and

3. A MOC that received a score of 70%-74% is approved for one year.

D. CMS is also proposing to provide an opportunity for a SNP to cure deficiencies in its MOC once per scoring cycle if the MOC fails to meet the minimum element benchmark or the aggregate minimum benchmark when reviewed and scored. A SNP that needed to use the cure process to reach a passing aggregate score will receive only a 1-year approval under the proposal.

ii. CMS is proposing to codify current policies and procedures for an MA organization to amend its MOCs after NCQA approval, as announced in the CY 2016 Final Call Letter:

A. MA Organizations that need to revise their MOC mid-cycle (off-cycle MOC

submission) during their MOC approval period may submit the revised MOC for review by NCQA between June 1st and November 30th of each calendar year or when CMS deems it necessary to ensure compliance with applicable standards and requirements.

B. SNPs may not implement any changes to a MOC until NCQA has approved the changes. The revised MOCs will not be scored (changes cannot be made to improve a score), and the successful revision of a MOC does not change the MOC's original period of approval.

C. C-SNPs are prohibited from submitting an off-cycle MOC submission except when CMS requires and off-cycle submission to ensure compliance with applicable regulations.

D. SNPs will have one opportunity to cure deficiencies.

E. SNPs will be prohibited from submitting off-cycle submission until the approved MOC has gone into effect.

g. Clinical Trial-Related Provisions (§§ 422.101 and 422.109) (pgs. 125-126)

i. CMS is proposing to adopt regulations regarding MA coverage of clinical trials covered by Medicare to ensure clarity on the coverage rules. The proposals generally codify existing guidance:

A. Traditional Medicare is responsible for coverage of routine costs of qualifying clinical trials for MA enrollees for clinical trials covered under the Clinical Trials National Coverage Determination 310.1 and all reasonable and necessary items and services used to diagnose and treat complications from participating in clinical trials.

B. MA enrollees participating in clinical trials are not subject to Part A and B deductibles.

C. MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred and the MA plan's in-network cost-sharing for the same category of items or services. The enrollee's in-network cost-sharing portion must be included in the plan's maximum out-of-pocket (MOOP) calculation.

D. MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial under NCD 310.1.

E. MA organizations must provide coverage for services to diagnose conditions covered by clinical trial services; most services furnished as follow-up care to clinical trial services; and services already covered by the MA organization.

ii. MA organizations are responsible for payment of claims related to enrollees' participation in both Category A and B investigational device exemption (IDE) studies. MA plans are responsible for payment of routine care items and services and coverage of CMS-approved Category B devices. A MA plan may apply utilization management, including prior authorization.

iii. MA plans are required to cover NCDs, including those that have a trial or registry component under Coverage with Evidence Development (CED). MA plans may apply utilization management, including prior authorization, to Medicare benefits covered under the NCD, consistent with MA program regulations.

h. Required Notice for Reinstatements Based on Beneficiary Cancellation of New

Enrollment (§§ 422.60 and 423.32) (pgs. 126-127)

i. To provide transparency and stability for stakeholders, CMS is proposing to require that MA and PDP plans must notify an individual when the individual's enrollment is reinstated due to the individual's cancellation of enrollment in a different plan.

ii. A reinstatement is generally not allowed if the individual intentionally initiated a disenrollment and did not cancel the disenrollment prior to the disenrollment effective date.

iii. When a beneficiary is automatically disenrolled from their plan because of enrollment in a new plan, but then cancels the request to enroll in the new plan within established timeframes, the associated automatic disenrollment from the previous plan becomes invalid.

iv. CMS proposes that the organization from which the individual was disenrolled send the member notification of the enrollment reinstatement within 10 days of receipt of the Daily Transaction Reply Report confirmation of the individual's reinstatement.

i. Part D Plan Failure to Submit Disenrollment Timely (§ 423.36) (pg. 127)

i. To provide transparency and consistency for stakeholders, and align the Part D regulation with the requirements for MA organizations, CMS proposes to codify the longstanding sub regulatory guidance to reflect that if the Part D sponsor fails to submit a disenrollment notice to CMS timely as required, such that the Part D sponsor received additional capitation payments from CMS, the Part D sponsor must reimburse CMS for any capitation payment received after the month in which payment would have ceased if the requirement had not been met timely.

j. Codify Existing Policy "Incomplete Disenrollment Requests" (§§ 422.66 and 423.36) (pgs. 127-128)

i. CMS has historically provided the procedural steps for plans to address incomplete disenrollment requests, including provided that when the disenrollment request is incomplete, plans must document efforts to obtain information to complete the request, and if any additional information needed to make the disenrollment request "complete" is not received within prescribed timeframes, the plan must deny the disenrollment request.

ii. CMS is proposing to codify these longstanding policies, and add that if the disenrollment request is incomplete, plans would be required to notify the individual within 10 calendar days of receipt of the disenrollment request.

A. Incomplete disenrollment requests received during the annual election period (AEP) must be received by December 7, or within 21 calendar days of the plan sponsor's request for additional information, whichever is later.

B. For all other election periods, required information must be received by the end of the month in which the disenrollment request was initially received, or within 21 calendar days, whichever is later.

C. If any additional information needed to make the disenrollment request complete is not received within those timeframes, the request must be denied.

k. Reinstatement of Enrollment for Good Cause (§§ 417.460, 422.74 and 423.44) (pgs. 128-129)

i. CMS is proposing to codify the current policy for MA organizations, Part D sponsors, or entities offering cost plans, as established in sub regulatory guidance, that reinstatement

for good cause will occur only when the individual requests reinstatement within 60 calendar days of the disenrollment effective date and that an individual may make only one reinstatement request for good cause in this 60-day period.

l. Required Notices for Involuntary Disenrollment for Disruptive Behavior (§§ 417.460, 422.74 and 423.44) (pgs. 129-130)

i. CMS is proposing to codify current policy for MA, Part D, and cost plan notices during the disenrollment for disruptive behavior process. The notices provide the beneficiary with a warning of the potential consequences of continued disruptive behavior. To request approval of a disenrollment for disruptive behavior, an MA organization, Part D plan, or cost plan would be required to provide two notices:

A. An advance notice, informing the plan member that continued disruptive behavior could lead to involuntary disenrollment; and

B. A notice of the plan's intent to request CMS permission to disenroll the member, sent at least 30 days after the advance notice to give the member an opportunity to cease the behavior.

C. The notices must also convey information that the individual has the right to use the plan's grievance procedures.

D. Plans would be required to submit dated copies of the required noticed to CMS along with other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

m. Codification of the Part D Optional Disenrollment for Fraud and Abuse Policy (§ 423.44) (pgs. 130-131)

i. CMS is proposing to codify the policy for optional disenrollment from a Part D plan based on an individual providing fraudulent information on her or her election form or permitting abuse of his or her enrollment card.

ii. A Part D plan who opts to disenroll an individual who commits fraud or permits abuse of their enrollment card must provide the individual a written notice of the disenrollment that meets the following notice requirements:

A. A written notice of disenrollment to the member to advise them of the plan's intent to disenroll; and

B. The plan must report to CMS any disenrollment based on fraud or abuse.

n. SPAP or Other Payer Exception for Disenrollment for Failure to Pay (§ 423.44) (pg. 131)

i. To protect beneficiaries who have SPAPs, or other payers, cover their premiums, CMS proposes to codify current policy that excepts members for which the plan has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer.

o. Possible End Dates for the SEP for Government Entity-Declared Disaster or Other Emergency (§§ 422.62 and 423.38) (pgs. 131-132)

i. In order to clarify the length of the SEP, CMS is proposing:

A. For state or local emergencies/disasters, the end date for the SEP may also be based on an emergency/disaster order automatically expiring pursuant to a State or local law, if such a law exists. The SEP ends based on the end of the

emergency/disaster period, regardless of whether the period ends based on an announcement by the applicable authority or expires based on applicable State or local law.

B. If no end date for the period of disaster/emergency is otherwise identified, the automatic incident end date will be 1 year after the SEP start date (14 months in length).

p. Updating MA and Part D SEPs for Changes in Residence and Codifying Procedures for Developing Addresses for Members Whose Mail is Returned as Undeliverable (§§ 422.62, 422.74, 423.38 and 423.44) (pgs. 132-133)

i. Codifies current SEP policy as reflected in CMS's existing sub regulatory guidance and that is being carried out currently by MA organizations and Part D plan sponsors.

ii. Codifies current policy for temporary absences from the plan service area, the sources of information on which plan sponsors may make related eligibility determinations, and the implications for disenrollment.

iii. Aligns the Part D regulation with MA regulation by amending § 423.44(d)(5)(i) to state that a PDP must disenroll an individual if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area.

iv. Proposes to amend § 422.74 by adding paragraphs (d)(4)(ii)(A) and (d)(4)(iii)(F) for MA and to amend § 423.44 by revising paragraph (d)(5)(ii) for Part D to state that an individual is considered to be temporarily absent from the plan service area when any one or more of the required materials and content referenced in §§ 422.2267(e) and 423.2267(e), if provided by mail, is returned to the plan sponsor by the US Postal Service as undeliverable and a forwarding address is not provided.

q. Codify the Term "Whole Calendar Months" (§§ 422.74 and 423.44) (pgs. 134-135)

i. Proposes to revise §§ 422.74(d)(1)(i)(B)(1) and 423.44(d)(1)(iii)(A) to include the requirement that the grace period be at least two whole calendar months, to begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

r. Researching and Acting on a Change of Address (§§ 422.74 and 423.44) (pgs. 135)

i. Proposes to amend the MA and Part D regulations to include the requirement that plans document their efforts to determine an enrollee's residency status.

ii. Proposes to codify at § 422.74(d)(4)(i) and at § 423.44(d)(5)(i) and (d)(5)(ii) that MA organizations and Part D plan sponsors must document the basis for involuntary disenrollment actions that are based on the residency requirements.

iii. Codifies current disenrollment notice policy, as reflected in § 50.2.1.5 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.6 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, and also codify the current documentation policy that is currently reflected in § 50.2.1.3 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

s. Part D Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members (§§ 423.32 and 423.36) (pgs. 135-136)

i. Codifies existing Part C requirement for Part D to allow an exception for employer/union group health plan (EGHP) sponsors to process election forms for Medicare-entitled group

members (63 FR 52612, 63 FR 35071).

ii. Specifically, proposes at new §§ 423.32(i) and 423.36(e) to permit a Part D plan sponsor that has a contract with an employer or union group to arrange for the employer or union to process enrollment and disenrollment elections for Medicare-entitled group members who wish to enroll in or disenroll from an employer or union sponsored Part D plan.

iii. Aligns the Part D regulation with the requirements that MA organizations follow in existing Part C regulations at §§ 422.60(f) and 422.66(f) and codify existing policies in the sub-regulatory guidance in Chapter 3 of the Medicare Prescription Drug Benefit Manual.

t. Single-Tier Benefit Requirement for Defined Standard Coverage (§§ 423.100, 423.120,423.2267) (pgs. 136-137)

i. Codifies current sub regulatory policy that a plan offering Defined Standard coverage apply a single-tier benefit structure to drugs on its formulary (if it uses a formulary, as defined at § 423.4).

ii. Proposes to codify sub regulatory policy that all communications and marketing materials (as these terms are defined at § 423.2260) for a plan offering Defined Standard coverage must reflect a single-tier benefit structure.

iii. Propose to define the term “formulary crosswalk” at § 423.100 as the process during bid submission by which a formulary (as defined at § 423.4) is assigned to one or more Part D plans with single- or multi-tier benefit structures.

iv. Proposes to add new paragraph § 423.120(b)(9) to codify that a Part D plan offering Defined Standard coverage may not apply multi-tier benefit structures to the formulary (as defined at § 423.4) to which it has been assigned via the formulary crosswalk (as defined at § 423.100) as part of the bid submission process.

v. Proposes to codify sub regulatory policy that a plan offering Defined Standard coverage display a single-tier benefit structure in all relevant marketing and communications materials. Specifically, at new § 423.2267(e)(42), proposes to require that, when discussing the Part D plan’s formulary, a plan offering Defined Standard coverage convey that all covered drugs have a single-tier benefit structure. This would be model content included in all relevant communications and marketing materials (as defined at § 423.2260) that pertain to the formulary or preferential status of the covered Part D drugs – including the complete and abridged formulary, Summary of Benefits, Evidence of Coverage, and other materials, as applicable.

u. Shortages of Formulary Drug Products During a Plan Year (§ 423.120) (pgs. 137-138)

i. Proposes to codify existing sub regulatory guidance, first released in the July 21, 2009 Health Plan Management System (HPMS) memorandum titled “Shortages of Formulary Drug Products During a Plan Year” and subsequently incorporated into chapter 5 of the Prescription Drug Benefit Manual, describing expectations of Part D sponsors when shortages impact drugs on their Part D plan formulary.

ii. Proposes to add a new paragraph (g) to § 423.120 to specify that proposed drug shortage requirements would apply in the case of shortages listed on the FDA website at https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages and corresponding database at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm . If a shortage becomes market withdrawal and therefore the product is no longer listed on the FDA drug shortage website, then the proposed requirements would no longer apply.

iii. Proposes a new paragraph § 423.120(g)(1) to require Part D sponsors to permit enrollees affected by a shortage to obtain coverage for a therapeutically equivalent drug or an interchangeable biological product, if any, for at least the duration of the shortage.

iv. As proposed at § 423.120(g)(1)(i), Part D sponsors would be required to permit enrollees affected by a shortage to obtain coverage for a therapeutically equivalent or interchangeable non-formulary alternative without requiring those enrollees to meet formulary exception requirements at § 423.578(b).

v. In the case where a therapeutically equivalent or interchangeable alternative is on the formulary but requires prior authorization or step therapy, as proposed at § 423.120(g)(1)(ii), Part D sponsors would be required to permit enrollees affected by a shortage to obtain coverage for the formulary alternative without requiring those enrollees to satisfy prior authorization or step therapy requirements.

vi. Proposes, at new paragraph (g)(2), to specify that the Part D sponsor would not be required to charge the cost sharing that applies to the unavailable formulary product for the alternative product and may charge the applicable sharing that would apply to the alternative therapeutically equivalent or interchangeable product's formulary status and the plan benefit design.

A. If the alternative product is on the formulary, the enrollee would be expected to pay the cost sharing that would normally apply based on the plan benefit design and if the alternative product is non-formulary, then the enrollee would be expected to pay the cost sharing associated with formulary exceptions.

vii. Part D sponsors would be required to cover a therapeutically equivalent drug or interchangeable biological product as an alternative to the formulary product subject to shortage if there is claim submitted for the alternative but Part D sponsors may work with enrollees and providers to determine appropriate alternative drugs since suitable options may vary based on clinical needs, costs, or other factors.

viii. Would not require changes to the Part D sponsor's formulary; rather, they would require, for the duration of a shortage, coverage of alternative therapeutically equivalent products in lieu of the product in shortage.

v. Validity of DEA Registration Numbers for Controlled Substances (§ 423.120(c)) (pg. 138-140)

i. Propose to amend § 423.120(c) to codify in regulation the current policy that Part D sponsors must confirm the validity of a prescriber's Drug Enforcement Administration (DEA) registration number for a controlled substance, if the number is on the drug claim. Or, if the prescriber's DEA registration number is not on the Part D claim, the sponsor must use prescriber identifier data sources to cross-reference the prescriber's individual National Provider Identifier (NPI) number, which is required on all Part D drug claims,164 to the prescriber's DEA registration number for validation.

ii. Proposes to codify the above required verifications for Schedule II-V drug claims.

iii. Proposes that sponsors be required to confirm that the controlled substance prescribed is consistent with the prescriber's DEA Schedule registration.

iv. Proposes that if a Part D sponsor finds a valid and active DEA registration number for the prescriber of a controlled substance, and an associated schedule that is appropriate for the drug, then the sponsor must process the claim under the other coverage parameters of applicable Part D plan. If the sponsor finds a DEA registration number, but it is not valid or active, or the associated schedule for the drug is not appropriate, the

sponsor must reject the claim and send the pharmacy an electronic code with the reason for the rejection.

A. The sponsor should not return the designated code to trigger the delivery of the standardized pharmacy notice to the enrollee, as the claim has been rejected because it does not contain all necessary data elements for adjudication.

B. For written member requests for reimbursement, proposes that if the Part D sponsor determines that the DEA registration number of the prescriber was not valid or not active or there was not an associated schedule that was consistent with the drug for which the member requested reimbursement, then the Part D sponsor not only must deny the member request for reimbursement, but must also provide the beneficiary with a written notice explaining the coverage determination consistent with the notice requirements at § 423.568(g).

v. Proposes that if there is no individual prescriber DEA registration number found to validate, a Part D sponsor is not required to take any further action when processing a claim for a controlled substance in terms of validating a DEA registration number. The sponsor must check the validity of the DEA registration number only when there is an individual prescriber DEA registration number associated with the Type I NPI on the Part D claim.

vi. Solicits comment on whether CMS should require sponsors to reject all claims for controlled substances for which they cannot validate the DEA registration number and schedule, and what impact this adjustment in policy would have on beneficiary access to controlled substances covered by Part D, if any.

w. Codifying Current Part D Transition and Continuity of Care Policies (§§ 423.100 and § 423.120) (pgs. 140-143)

i. Propose to codify policies with respect to 1) quantity limits (QLs); 2) the minimum 108-day lookback period; 3) P&T committee role in transition; 4) transition notice timeframes; 5) level of care changes; and 6) (LTC) emergency supply.

ii. Quantity Limits (QLs) During Transition

A. Proposes to add to § 423.120(b)(3) that certain quantity limits (QLs) would require a sponsor to provide for an appropriate transition for an enrollee if the Part D drug is on the plan's formulary. This proposal, if finalized, would apply both for a current enrollee when a QL has been added to a drug on the plan's formulary that is lower than the beneficiary's current dose, and for a new enrollee when an existing QL for a formulary drug is lower than the beneficiary's current dose. (Consistent with CH. 6, Section 30.4)

B. Propose that QLs that are "safety-based claim edits," meaning those claim edits that are consistent with drug utilization review (DUR) requirements described at § 423.153(c)(2) to prevent unsafe or inappropriate dosing, would continue to be applied to transition supplies.

C. Proposes that § 423.120(b)(3) would state that a Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary, including Part D drugs that are on a sponsor's formulary, require prior authorization, step therapy, or under a plan's drug utilization management rules, are subject to a quantity limit that is not a safety-based claim edit as defined in § 423.100.

D. Proposes to make a conforming change to § 423.120(b)(3)(iii) to include a reference

to QLs and solicits comments on this proposal.

iii. Minimum 108-day Lookback Period

A. Proposes to codify current policy by requiring at § 423.120(b)(3)(vii)(A) and (B) that, if a Part D sponsor has access to prior drug claims history for the enrollee (through an affiliated plan or otherwise), the sponsor must use a minimum 108-day claims history lookback period to determine at point-of-sale whether a pharmacy claim represents a new prescription which would not require a transition fill, or ongoing drug therapy which would require a transition fill.

B. If a Part D sponsor does not have access to prior claims history for the enrollee and cannot determine at point-of-sale whether a pharmacy claim represents a new prescription or ongoing therapy, the sponsor must treat the prescription as ongoing therapy which would require a transition fill.

iv. Pharmacy & Therapeutics (P&T) Committee Role in Transition

A. Codifies the P&T Committee's role in transition by adding new requirements at § 423.120(b)(3)(viii) to require that the Part D sponsor's transition policies and procedures include assurances that the Part D sponsor's P&T Committee has reviewed, provided recommendations as warranted, and approved the plan's transition policies and procedures to comply with § 423.120(b)(3).

B. Propose to codify current sub regulatory guidance that such policies and procedures must be submitted through a process specified by CMS as part of the plan's annual bid.

v. Timing Clarifications for Transition Notices

A. Proposes to specify in § 423.120(b)(3)(iv) that the first business day after adjudication of the transition fill – that is, the processing of the claim – counts as business day for purposes of calculating the three business days allowed for sending the transition notice.

vi. Level of Care Changes

A. Proposes a new paragraph § 423.120(b)(3)(i)(A)(5) to require Part D sponsors to apply their transition processes to current enrollees experiencing a level of care change, such as admission or discharge from a hospital, skilled nursing facility, long-term care facility, and hospice.

B. Acknowledges that a Part D sponsor may not have access to information about an enrollee's level of care changes and proposes new § 423.120(b)(3)(i)(A)(5) to specify that the sponsor would have to apply its transition process to enrollees experiencing a level of care change only if the sponsor were notified of such change by the enrollee or their representative, their prescriber, the hospital or facility, or a pharmacy before or at the time of the request for the fill referenced in § 423.120(b)(3)(iii). Such notification could be by electronic messaging.

vii. LTC Emergency Supply

A. Proposes to codify policy in section 30.4.6 that Part D sponsors must also cover emergency supplies of new starts of non-formulary Part D drugs for LTC facility residents, outside of any respective transition periods for them, while an exception or prior authorization request is being processed by adding add a paragraph (8) to § 423.120(b) that would require a Part D sponsor to cover such an emergency supply during any portion of the plan year when the enrollee did not otherwise qualify

for a transition fill under § 423.120(b)(3).

B. Proposes that for purposes of a LTC emergency fill requirement, "non-formulary" would have the same meaning as it does for transition fills at paragraph (b)(3) – that is, a non-formulary drug also means drugs that are on the Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization, step therapy, or are subject to a QL that is not a safety-based claim edit as defined in § 423.100 under the plan's drug utilization management rules).

C. Proposes that this emergency supply must be for at least 31 days of medication, regardless of dispensing increments, unless the prescription is written by a prescriber for less than 31 days.

viii. Summarizes and solicits comments on all above proposals (pgs. 448-450).

x. Update of Terminology to "Individuals with Intellectual Disabilities" (§ 423.154) (pg. 143)

i. Proposes to update the current language at § 423.154(c) (intermediate care facilities for the mentally retarded) with the abbreviation (ICFs/IID) and the definition at § 435.1010. and to replace the term "the mentally retarded" at § 423.154(c) with "individuals with intellectual disabilities." As it was inadvertently missed in prior changes.

y. Technical Correction to Restore the Substantial Difference Requirement (§ 423.265) (pg. 143)

i. Proposes to make a technical correction to § 423.265(b)(2) to restore language on requirements for substantial differences between Medicare Part D sponsors' bids that was inadvertently removed in a recent revision of the section.

z. Part D Global and Targeted Reopenings (§§ 423.308 423.346) (pgs. 143-146)

i. For reopening of a Part D payment reconciliation, proposes to codify the definitions of "global reopening" and "targeted reopening." and to modify the timeframe for performing a reopening for good cause from within 4 years to within 6 years to align with the 6-year overpayment look-back period described at § 423.360(f) and to help ensure that payment issues, including overpayments, can be rectified.

ii. Propose to codify the circumstances under which CMS will notify the sponsor(s) of our intention to perform a reopening and the requirement for CMS to announce when it has completed a reopening.

iii. Proposes to modify § 423.346(a)(2) such that CMS may reopen and revise an initial or reconsidered final payment determination after the 12-month period (described at § 423.346(a)(1)), but within 6 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening. This proposed change will allow CMS to process all changes to PDE data and DIR data after the overpayment look-back period for a contract year. Once a contract year falls outside the lookback period, CMS would perform the global reopening for that contract year within the new proposed 6-year timeframe, and in doing so, would recoup the PDE and DIR related overpayments reported by sponsors for that contract year (as well as process underpayments).

iv. Proposes standards for reopening including that in order to be included in a reopening, a contract must have been in effect (that is, receiving monthly prospective payments and submitting PDE data for service dates in that year) for the contract year being reopened and that if CMS has sent a nonrenewed or terminated contract the "Notice of final settlement," as described at proposed § 423.521(a), by the time CMS completes the

reopening, described at proposed § 423.346(f), CMS will exclude that contract from that reopening.

v. Propose at § 423.346(g)(2) that, specifically for targeted reopenings, CMS will identify which contracts or contract types are to be included in the reopening and notify sponsors of this specific inclusion criteria via the proposed reopening notification and/or the proposed reopening completion announcement.

vi. Proposes to add new paragraphs at § 423.346 to codify existing policy regarding reopening notifications and reopening completion announcements, including codifying at § 423.346(e) that CMS will notify the sponsor(s) that will be included in the global or targeted reopening of its intention to perform a global or a targeted reopening – that is, the sponsor would receive prior notice of the reopening—only when it is necessary for the sponsor(s) to submit PDE data and/or DIR data prior to the reopening. In contrast, if it is not necessary for the sponsor(s) to submit data prior to a reopening, we propose to notify the sponsor(s) only after CMS has conducted the reopening.

vii. Proposes that CMS will include in the notification the deadline for submitting PDE data and/or DIR data to be included in the reopening, that the deadline to submit this data will be at least 90 calendar days after the date of the notice, that the reopening notification will include inclusion criteria in the form of a description of the contract(s) (either specifically by contract number or generally by contract-type or contract status) that will be included in the reopening, that CMS will announce when it has completed a reopening, that CMS will provide a description of the data used in the reopening,

viii. Specifies the proposed content of the reopening and completion notifications.

aa. Part D Proposed Automatic Shipment Requirements (§ 423.505) (pgs. 146-148)

i. Propose to codify in regulation auto-ship policies with appropriate safeguards to prevent or limit unwanted or unnecessary auto-shipped prescriptions.

ii. Specifically, proposes to add a new paragraph at § 423.505(b)(28) to require Part D sponsors to require their network pharmacies that offer auto-ship services to--

A. Provide automatic shipments only to Part D enrollees that opt-in, on a drug-by-drug basis, after an initial fill;

B. Provide a minimum of two (2) shipping reminders to the Part D enrollee prior to shipment through auto-ship services. Such reminders would need to be received prior to shipment so that a Part D enrollee can modify or cancel an order, if needed. Part D sponsors may specify an approximate shipping date range (for example, 2-3 calendar days) in lieu of an exact date in shipping reminders;

C. Refund any cost sharing paid by the Part D enrollee for any shipped prescriptions that such Part D enrollee reports as unneeded or otherwise unwanted, regardless of whether the drug is returned to the pharmacy and reverse the claim. Part D sponsors would be required to delete the associated Prescription Drug Event (PDE) for these reversed claims.

iii. Proposes to add new paragraph § 423.505(b)(28)(ii)(B) to specify that network pharmacies must provide the shipping reminders by hard copy mailing, telephone, electronic delivery, or other comparable means of communication such as a fax machine. The method of delivery should be based on the Part D enrollee's stated preference when feasible. A missed call with no message left, bounce-back e-mail messages, or returned direct mailings would not count as successful shipping reminders because they indicate that the enrollee never received the reminder.

iv. Proposes to add for § 423.505(b)(28)(ii)(C) the requirement that all types of reminders must, at a minimum, include the name of the Part D drug, any applicable cost sharing, the scheduled shipping date, instructions on how to cancel the pending automatic shipment, and instructions on how to opt-out of any future automatic shipments. In turn the pharmacy would be required to honor the request to cancel the specified drugs from further auto shipment.

v. Proposes to add new paragraph § 423.505(b)(28)(iv) to require Part D sponsors to require their network pharmacies that offer auto-ship services to discontinue auto-ship services if A) the enrollee requests to opt-out of automatic shipments or B) the network pharmacy receives notification that a Part D enrollee entered a skilled nursing facility (SNF) or elected hospice.

vi. Summarizes proposals and solicits comments

bb. Part D Subcontractors May Terminate Only at the End of a Month (§ 423.505) (pgs. 148-149)

i. Proposes to require Part D sponsors to include a provision in certain contracts with first tier, downstream, and related entities (FDRs) (as defined at § 423.501) that the FDR may terminate its contract only at the end of a calendar month after providing at least 60 days' prior notice. Specifically, proposes that this prior notice be required in contracts with FDRs that perform critical functions on the sponsor's behalf, as discussed below.

ii. The functions for which this requirement would apply would be:

A. Authorization, adjudication, and processing of prescription drug claims at the point of sale;

B. Administration and tracking of enrollees' drug benefits in real time;

C. Operation of an enrollee appeals and grievance process; and

D. Contracting with or selection of prescription drug providers (including pharmacies and non-pharmacy providers) for inclusion in the Part D sponsor's network.

cc. Application of Two-Year Ban on Reentering the Part D Program Following Non-renewal (§§ 423.507 and 423.508) (pgs. 149-150)

i. Proposes to amend §§ 423.507(a)(3) and 423.508(e) to clarify that the prohibition on PDP sponsors that non-renew or mutually terminate a contract receiving a new PDP contract for two years applies at the PDP region level. That is, if a sponsor non-renews or mutually terminates a PDP contract, the two-year exclusion would only prohibit them from receiving a new or expanded PDP contract in the PDP region(s) they exited and would not prevent them from receiving a new or expanded contract in another region(s).

ii. Proposes to clarify that that the two-year exclusion applies whenever a PDP sponsor terminates all of its benefit packages (PBPs) in a PDP region, commonly known as a "service area reduction," even if they continue to serve other PDP regions under the contract.

iii. Proposes to authorize CMS to make organizations that non-renew all of their PBPs in a PDP region ineligible to have plan bids approved again in that region for two years

iv. Exempts EGWP PBPs from the two year ban.

dd. Crosswalk Requirements for Prescription Drug Plans (§ 423.530) (pgs. 150-155)

i. Proposes to codify, with modifications, the current process and conditions under which

PDP sponsors can transfer their enrollees into a different PDP's plan benefit packages (PBPs) from year to year when such enrollees have made no other election.

ii. Defines plan crosswalks and crosswalk exceptions, codifies the circumstances under which enrollees can be transferred into different PDP PBPs from year to year, establishes the circumstances under which enrollees can be transferred into PDP PBPs offering different types of prescription drug coverage ("basic" or "enhanced alternative" coverage), establishes the circumstances under which enrollees can be transferred due to contract consolidations of PDPs held by subsidiaries of the same parent organization, and provides protections against excessive premium increases resulting from crosswalks.

iii. Proposes to limit the ability of PDP sponsors to create new PDP PBPs to replace non-renewing PBPs under certain circumstances.

iv. Requests comment on whether and under what circumstance CMS should permit crosswalks from PBPs offering basic prescription drug coverage to PBPs offering enhanced prescription drug coverage, whether CMS should require sponsors that non-renew an enhanced alternative PBP while continuing to offer individual market coverage in the same PDP region to crosswalk affected beneficiaries into another PBP, and on limitations CMS should place on premium and cost increases for enrollees who are crosswalked between different PBPs. CMS is particularly interested in how best to balance avoiding gaps in prescription drug coverage, preserving beneficiary choice and market stability, and preventing substantial increases in costs to beneficiaries resulting from crosswalks.

v. Proposes to codify the current procedures that a Part D sponsor must follow when submitting a crosswalk or crosswalk exception request.

vi. Proposes to limit the number of PDP contracts a parent organization may offer through its subsidiaries to one per PDP region.

vii. Proposes to adopt the crosswalk prohibitions in current CMS sub regulatory guidance, described in the PDP Renewal and Nonrenewal Guidance.

viii. Solicit comments on whether and under what circumstances to allow crosswalks from PBPs offering basic prescription drug coverage to enhanced alternative coverage. CMS is interested in how and to what extent permitting such crosswalks would affect the market for basic prescription drug coverage. CMS is particularly interested in how such crosswalks could be administered in a way that protects LIS eligible beneficiaries from premium and other cost increases.

ix. Proposes at § 423.530(b)(1) and (2) to require enrollees in PDP PBPs that are renewing to be transferred into the same PBP for the following contract year. This is consistent with the current process summarized for renewal plans in the PDP Renewal and Nonrenewal Guidance.

x. Proposes at § 423.530(c) to classify consolidated renewal and contract consolidation crosswalks as "crosswalk exceptions."

xi. Proposes at § 423.530(c)(1) to allow, but not require, plan crosswalks in consolidated renewal scenarios. PDP sponsors could request a crosswalk of enrollment from a non-renewing PBP to another PBP under the same contract, provided it meets the requirements CMS is proposing.

xii. Proposes change from current policy, at § 423.530(c)(1)(v), that when a PDP sponsor chooses to crosswalk in a consolidated renewal scenario, to require enrollees from non-

renewing PBPs offering enhanced alternative coverage to be crosswalked into the PBP that will result in the lowest premium increase.

xiii. Solicits comments on whether we should use other factors, such as differences in estimated out of pocket costs (OOPC) between the non-renewing and surviving PBPs, rather than simply the difference in plan premiums, to determine whether approving a plan crosswalk exception is the best option for enrollees in a non-renewing PBP. CMS is also requesting comments on whether to allow plan crosswalks to a higher premium plan if the difference between the higher premium plan and the lower premium plan is less than a certain dollar amount.

xiv. Proposes at § 423.530(c)(2)(vi) to prohibit plan crosswalks for consolidated renewals if the crosswalk would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), compared to the current year premium for the non-renewing PBP. CMS seeks comments on alternatives to using the base beneficiary premium

xv. Because of the compressed time frames between bid submission and approval, CMS would base its assessment of premiums for the following plan year on information received with the initial bids on the first Monday in June. Bids are subject to change during the bid negotiation process, so a premium increase that appears acceptable in June may be higher by the time final bids are approved in August. However, the timing of plan crosswalk exceptions and bid review prevent CMS from basing crosswalk exception approvals on final bid amounts. CMS is soliciting comments on whether this timing may result in manipulation of bids and whether another measure of beneficiary costs, such as estimated OOPC, would be a more reliable measure to use given the difficulty of basing crosswalk approvals on final approved bids.

xvi. Proposes major modification to CMS's policy for consolidated renewal crosswalks at § 423.530(c)(1)(vii) is that sponsors that fail to request and receive a plan crosswalk exception would not be permitted to offer a new enhanced alternative PBP for the contract year after they non-renew an enhanced alternative PBP.

xvii. Proposes requirements for contract consolidations that would reflect current sub regulatory policy, but with two significant differences that parallel the proposals with respect to consolidated renewals. For contract consolidations, consistent with current policy, propose at § 423.530(c)(2) to approve plan crosswalk exceptions from non-renewing PBPs into PBPs in the surviving contract when the surviving contract is held by the same sponsor or by a subsidiary of that sponsor's parent organization.

A. The non-renewing PDP contract and the surviving contract must be held by the same legal entity or by legal entities with the same parent organization;

B. The approved service area of the surviving contract must include the service area of the non-renewing PBPs whose enrollment will be crosswalked into the surviving contract;

C. Enrollment may be crosswalked between PBPs offering the same type of prescription drug coverage (basic or enhanced alternative); and

D. Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering basic prescription drug coverage.

xviii. Change - Would require plan crosswalks from non-renewing PBPs offering enhanced alternative coverage into the PBP that would result in the lowest premium increase.

xix. Change – Would prohibit plan crosswalks that would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), compared to the current year premium for the non-renewing PBP.

xx. Proposes to codify current procedures for submitting plan crosswalks and or making plan crosswalk exception requests at § 423.530(d), as described in "Bid Pricing Tool for Medicare Advantage Plans and Prescription Drug Plans" CMS-10142, posted for final comment pursuant to the Paperwork Reduction Act of 1995 at 87 Fed. Reg. 2441 (February 14, 2022).

xxi. Proposes that a Part D sponsor must submit all allowable plan crosswalks in writing through the bid submission process in HPMS by the bid submission deadline. Through the bid submission process, the Part D sponsor may indicate if a plan crosswalk exception is needed at that time; however, the Part D sponsor must also request a crosswalk exception through the crosswalk exception functionality in HPMS.

ee. Drug Management Program (DMP) Appeal Procedures (§ 423.562) (pg. 155)

i. Proposes a technical change to the wording at § 423.562(a)(1)(v) that would remove discretionary language as it relates to a Part D plan sponsor's responsibility to establish a DMP under § 423.153(f) with appeal procedures that meet the requirements of subpart M for issues that involve at-risk determinations. This would eliminate the discretionary language and improve consistency with § 423.153(f), which requires each Part D plan sponsor to establish and maintain a drug management program and include appeal procedures that meet the requirements of subpart M for issues involving at-risk determinations.

ff. Part D Sponsor Website Requirements (§§ 423.2265(b)(12) and 423.2265(c)(1)(vi)) (pg. 155)

i. Proposes a technical correction to delete a duplicate reference to the prescription drug transition policy, as this information is already listed as required website content at § 423.2265(b)(10). Proposes to remove the reference to the "Prescription Drug Transition policy" at paragraph (b)(12) and redesignate that paragraph as reserved.

ii. Proposes to clarify the requirements at § 423.2265(c)(1)(vi) to be consistent with longstanding policy. Specifically, clarifies that a Part D sponsor's utilization management criteria, as approved by CMS, must be posted (whether in a form or other format) on the plan's website by October 15 prior to the plan year.

gg. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors that are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522) (pgs. 155-160)

i. Propose to amend 42 CFR part 422, subpart K, and part 423, subpart K, to codify in regulation our final settlement process for MA organizations and Part D sponsors whose contracts with CMS have been consolidated with another contract, non-renewed, or otherwise terminated. (codifies existing guidance pertaining to procedures for the final settlement process)

ii. Proposes to add a new appeals process for MA organizations or Part D sponsors that disagree with the final settlement amount. MAOs or Part D sponsors may request an appeal of the final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement. Failure to request appeal within 15 calendar days of the date of issuance of the notice of final settlement would indicate acceptance of the final

settlement amount.

A. The MA organization or Part D sponsor would have to specify the calculations with which they disagree and the reasons for their disagreement, as well as provide evidence supporting the assertion that CMS' calculation of the final settlement amount described in the notice of final settlement is incorrect.

B. MA organizations and Part D sponsors would not be able to submit new reconciliation data or data that was submitted to CMS after the final settlement notice was issued.

C. CMS would not consider information submitted for the purpose of retroactively adjusting a prior reconciliation.

D. CMS would not accept requests for appeal that are submitted more than 15 calendar days after the date of issuance of the notice of final settlement.

E. Once CMS has reconsidered the calculation of the final settlement amount in light of the evidence provided by the MA organization or Part D sponsor, CMS would provide written notice of the reconsideration decision to the MA organization or Part D sponsor.

iii. Proposes to add two additional levels of appeal:

A. An informal hearing conducted by the CMS Office of Hearings to review CMS' initial determination, following a request for appeal of the reconsideration of CMS' initial determination

1. If the MA organization or Part D sponsor does not agree with CMS's reconsideration decision, it would be able to request an informal hearing from a CMS hearing officer.

2. The MA organization or Part D sponsor would have to submit a request for review within 15 calendar days of the date of CMS's reconsideration decision.

3. The MA organization or Part D sponsor would be required to provide a copy of CMS' decision, the findings or issues with which it disagrees, and the reasons why it disagrees with CMS' decision.

4. As the hearing officer's review would be limited to a review of the existing record, the MA organization or Part D sponsor would not be able to submit new evidence to support its assertion that CMS' calculation of the final settlement amount described in the notice of final settlement is incorrect in addition to the evidence submitted during CMS' reconsideration.

5. CMS would provide written notice of the time and place of the informal hearing at least 30 days before the scheduled date and would provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer.

6. The CMS hearing officer would not receive new testimony or accept new evidence in addition to the evidence submitted by the MA organization or Part D sponsor during CMS' reconsideration to support its assertion that CMS' calculation of the final settlement amount is incorrect.

7. Once the hearing officer has reviewed the record, the hearing officer

would send a written decision to the MA organization or Part D sponsor explaining the basis of the hearing officer's decision. The hearing officer's decision would be final and binding unless the decision is reversed or modified by the CMS Administrator.

B. A review by the CMS Administrator of the hearing officer's determination if there is an appeal of the hearing officer's determination.

1. If the MA organization or Part D sponsor does not agree with the hearing officer's decision, they would be able to request an additional, final review from the CMS Administrator.
2. The MA organization or Part D sponsor would have to submit a request for review within 15 calendar days of the date of the issuance of CMS hearing officer's decision.
3. The MA organization or Part D sponsor would be able to submit written arguments to the Administrator for review but would not be able to submit evidence in addition to the evidence submitted during CMS' reconsideration.
4. The CMS Administrator would have the discretion to elect to review the hearing officer's decision or decline to review the hearing officer's decision within 30 calendar days of receiving the request for review.
5. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision would be final and binding.
6. If the Administrator elects to review the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor, the Administrator would review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor and determine whether to uphold, reverse, or modify the hearing officer's decision.
7. The Administrator's decision would be final and binding and no other requests for review would be considered.

iv. If an MA organization or Part D sponsor that owes a final settlement amount to CMS does not request an appeal or provides an optional response acknowledging and confirming the amount owed to CMS within 15 calendar days of the date of the notice of final settlement, the MA organization or Part D sponsor would be required to remit full payment to CMS within 120 calendar days of receiving the notice of final settlement.

v. If an MA organization or Part D sponsor is owed money and does not appeal the final settlement amount, CMS would remit payment to the MA organization or Part D sponsor within 60 calendar days of the date of issuance of the notice of final settlement.

vi. If an MA organization or Part D sponsor does not owe or is not owed a final settlement amount and does not request an appeal of the $0 final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement, no further actions would occur.

vii. Proposes to add definitions for final settlement amount and final settlement process.

viii. Proposes to add §§ 422.528 (for MA) and 423.521 (for Part D) to CMS regulations to codify the process for notifying MA organizations and Part D sponsors of the final

settlement amount and how payments to or from CMS would be made.

hh. Gross Covered Prescription Drug Costs (§423.308) (pgs. 160-162)

i. Proposes to amend the definition of "gross covered prescription drug costs" at § 423.308 to remove the phrase "actually paid." The proposed change would have no impact on Part D payment calculations or reporting requirements. Allowable reinsurance costs would continue to be defined at § 423.308 as the subset of gross covered prescription drug costs actually paid, so this proposed revision would not constitute a change in policy or require a change in operations under Part D,

5. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186) (pgs. 162 –184)

a. Introduction (pg. 162)

i. Unless otherwise stated, proposed changes would apply (that is, data would be collected, and performance measured) for the 2024 measurement period and the 2026 Star Ratings.

b. Contract Ratings (§§ 422.162(b) and 423.182(b)) (pgs. 162-163)

i. Propose to amend §§ 422.162(b)(1) and 423.182(b)(1) to add a sentence at the end to clarify that the overall and summary Star Ratings are calculated based on the measures required to be collected and reported for the contract type being offered for the Star Ratings year. This is current practice and how the Star Ratings have historically been calculated.

ii. Proposes to amend §§ 422.162(b)(3)(iv)(A)(1) and 423.182(b)(3)(ii)(A)(1) to clarify the calculation of the Part C and Part D improvement measures for contracts that consolidate. For the first year after a consolidation, we propose to clarify that the Part C and Part D improvement measures will not be calculated for the consolidated contract. The prior year measure-level scores only include data from the surviving contract; using those as the comparison point for a consolidated contract would not be an accurate comparison because it does not include any information about performance of the consumed contract(s). For the second year after a consolidation, the improvement measure is calculated, using the enrollment-weighted measure scores for the current and prior year because scores for both years are available for the consolidated contract. This is the current (and historical) process and how the proposed regulatory clarification will be applied.

iii. Proposes to revise the current regulation text at §§ 422.162(b)(3)(iv)(A)(1) and 423.182(b)(3)(ii)(A)(1) to clarify that the Part C and Part D improvement measures are not calculated for the first year after a contract consolidation. This proposal codifies the current application of the ratings rules.

c. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184) (pgs. 163-172)

i. Proposes to permanently remove the Diabetes Care – Kidney Disease Monitoring measure because it has been retired by NCQA and proposing to replace this measure with the Kidney Health Evaluation for Patients with Diabetes measure.

ii. Proposes to remove the Medication Reconciliation Post-Discharge (MRP) measure as it would be duplicative of the MRP component of the Transitions of Care (TRC) measure. Proposes to remove the stand-alone MRP measure from the 2026 Star Ratings for

measurement year 2024 since the same information about medication reconciliation is now also incorporated as a component of the TRC measure and, consequently, it is duplicative to have MRP as a stand-alone measure and as a component of the TRC measure.

iii. Proposes a substantive update to the existing colorectal cancer screening measure because of changes in the applicable clinical guidance and by NCQA. Proposes expanding the age range for the Colorectal Cancer Screening measure to adults age 45-49, for an updated age range of 45-75, for the 2024 and subsequent measurement years.

iv. Proposes to add the Care for Older Adults (COA) – Functional Status Assessment measure back to the Star Ratings after it has been on the display page following a substantive measure specification change. The COA measure is collected for Special Needs Plans (SNPs) and includes three indicators – Medication Review, Functional Status Assessment, and Pain Assessment.

v. Proposes to return this updated measure to the Star Ratings, beginning with the 2026 Star Ratings and 2024 measurement period. With the updated specification, documentation of a complete functional status assessment must include: (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; or (3) result of assessment using a standardized functional assessment tool. For weighting purposes, a substantively updated measure is treated as a new measure and will receive a weight of 1 for the first year and will be treated as a process measure in subsequent years.

vi. Proposes to implement risk adjustment (case-mix adjustment) based on sociodemographic status (SDS) characteristics, a substantive update, to the three Part D medication adherence measures for the 2028 Star Ratings (2026 measurement year). If finalized, the legacy medication adherence measures would remain in the Star Ratings and the updated medication adherence measures with the SDS risk adjustment would be on the display page for at least two years (beginning with the 2024 measurement year for the 2026 display page). Beginning with the 2026 measurement year and 2028 Star Ratings, CMS would then move the re-specified measures from display page to Star Ratings and the legacy measures would be removed under this proposal.

vii. Proposes to implement non substantive specification changes to adherence measures to (1) apply continuous enrollment (CE) instead of member-years (MYs) adjustment and (2) no longer adjust for stays in inpatient (IP) settings and skilled nursing facilities (SNFs).

viii. Proposes to add the Kidney Health Evaluation for Patients with Diabetes (KED) measure to the 2026 Star Ratings

ix. Proposes to add the following measures to the 2026 Star Ratings (2024 measurement year): COB, Poly-ACH, and Poly-CNS. Additionally, the measures will include a non-substantive update: to align with the PQA measure specifications by using continuous enrollment (CE) and no longer adjusting for member-years (MYs).

x. Provides a summary table of Proposed New and Revised Individual Star Rating Measures for Performance Periods Beginning on or after January 1, 2024 (pgs. 536-537)

xi. Proposes to add collection of survey data through another mode of survey administration to the non-exhaustive list of non-substantive measure updates that can be made without rulemaking. Proposes to clarify in the regulation that an expansion in the data sources used, whether by adding an alternative source of data or adding an alternative way to collect the data, is a non-substantive change in measure specifications.

xii. Proposes that CMS will have the authority to remove a measure from calculations of Star

Ratings when a measure steward other than CMS (such as NCQA or PQA) retires the measure. CMS continually reviews measures that are used in calculations of Star Ratings.

d. Measure Weights (§§ 422.166(e) and 423.186(e)) (pgs. 172-174)

i. Proposes to lower the weight of patient experience/complaints and access measures from 4 to 2 beginning with the 2026 Star Ratings covering the 2024 measurement period.

ii. Proposes to adopt regulation text clarifying how CMS treats measures with substantive updates when they return to the Star Ratings program. Proposes to add language to §§ 422.166(e)(2) and 423.186(e)(2) to clarify that when a measure with a substantive update moves back to Star Ratings from the display page following rulemaking, it is treated as a new measure for weighting purposes and therefore would receive a weight of 1 for its first year back in the Star Ratings program. This is consistent with current and prior practice. In subsequent years, the measure (both new measures and substantively updated measures) would be assigned the weight associated with its category, which is what happens with new measures as well.

e. Guardrails (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i)) (pgs. 174-175)

i. Proposes to modify the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) by eliminating the guardrails that restrict the maximum allowable movement of non-CAHPS measure cut points.

ii. Proposes at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to modify the language so that guardrails for non-CAHPS measures will only be effective through the 2025 Star Ratings released in October 2024, and not apply for the 2026 Star Ratings or beyond.

f. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3)) (pgs. 175-181)

i. Proposes a health equity index reward to further incentivize Part C and D plans to focus on improving care for enrollees with social risk factors (SRFs) to support CMS efforts to ensure attainment of the highest level of health for all people.

ii. Adds definition for health equity index at §§ 422.162 and 423.182 (means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.)

iii. The HEI reward is specifically designed to create an incentive to reduce disparities in care. The HEI, therefore, does not replace the CAI (designed to improve the accuracy of performance measurement) but rather assists plan sponsors in better identifying and then addressing disparities in care provided to members with a particular SRF, with the ultimate goal of reaching equity in the level and quality of care provided to enrollees with SRFs. There would be no changes to the current CAI with the implementation of the proposed HEI reward.

iv. Proposes to replace the current reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) with the new HEI reward at proposed §§ 422.166(f)(3) and 423.186(f)(3) starting with the 2027 Star Ratings; the HEI for the 2027 Star Ratings would be calculated using data collected or used for the 2026 and 2027 Star Ratings.

v. The removal of the current reward factor is contingent on finalizing the addition of the proposed HEI reward.

vi. The proposed HEI would summarize contract performance in relation to enrollees with certain SRFs across multiple existing Star Ratings measures into a single score using

data from the most recent two measurement years. CMS proposes at §§ 422.166(f)(3)(i)(A) and 423.186(f)(3)(i)(A) to initially include receipt of the LIS or being dually eligible (LIS/DE) or having a disability as the group of SRFs used to calculate the HEI.

A. For purposes of the HEI, CMS proposes to define an LIS/DE beneficiary as one who was designated as a full-benefit or partial-benefit dually eligible individual or who received a low-income subsidy (LIS) at any time during the applicable measurement period, as CMS does currently for the calculation of the CAI.

B. If a person meets the criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. CMS intends to use the original reason for entitlement to the Medicare program to identify enrollees with a disability for purposes of the HEI as we do for the calculation of the CAI.

C. CMS is interested in feedback on potential additional ways to identify enrollees who have a disability that could be incorporated over time and whether the same process and standards should be used for the CAI adjustment as well.

vii. The proposed HEI would examine performance among those with certain SRFs for all Star Ratings measures unless they meet one of the specified exclusions. As provided in proposed §§ 422.166(f)(3)(ii)(A)-(D) and 423.186(f)(3)(ii)(A)-(D), measures would be excluded from the HEI if one or more of the following criteria are met:

A. The focus of the measurement is not the enrollee but rather the plan or provider.

B. The measure is retired, moved to display, or has a substantive specification change in

C. Either year of data used to construct the HEI.

D. The measure is applicable only to SNPs.

E. At least 25 percent of contracts are unable to meet the criteria described at proposed paragraph (f)(3)(iv), which provides that a measure is only included for the HEI for a contract if the measure has a reliability of at least 0.7 for the contract when calculated for the subset of enrollees with the specified SRF(s) and the contract meets the measure denominator requirement when the measure is calculated for only the enrollees with the specified SRF(s) (that is, the SRFs included in the HEI). For Part D measures, this criterion is assessed separately for MA-PDs and cost contracts, and PDPs. (exclude any measures from the HEI that less than 25 percent of contracts can have reliably calculated because scores would be missing for most contracts).

viii. Proposes each of the five steps that CMS would take to analyze the measure-level scores for each contract and to roll up to the HEI scores in order to assess when an adjustment is available for a contract's ratings. (pgs. 556-559, with table summary on pg. 559)

ix. Proposes that in order to qualify for an HEI reward, contracts must have a minimum rating-specific HEI score of greater than zero and proposes a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified SRFs.

x. Proposes that contracts that have percentages of enrollees with any of the specified SRFs in a given year that are greater than or equal to one-half of the contract-level median percentage of enrollees with the specified SRFs up to, but not including, the contract-level median would qualify for one-half of the HEI reward. Contracts that have percentages of enrollees with any of the specified SRFs greater than or equal to the

contract-level median would qualify for the full HEI reward.

xi. Also considering an alternative non-tiered HEI reward structure, where all contracts with percentages of enrollees with any of the specified SRF greater than or equal to one-half of the contract-level median would qualify for the full HEI reward.

xii. Proposes at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) that the contract percentages of enrollees with SRFs included in the HEI would be based on enrollment in the most recent of the two years of data used to calculate the HEI.

xiii. Due to ineligibility for LIS, proposes at §§ 422.166(f)(3)(vii)(A) and (B) and 423.186(f)(3)(vii)(A) and (B) to use a modified calculation to determine the percentage of enrollees with SRFs included in the HEI for contracts with service areas wholly located in Puerto Rico.

xiv. Provides details of reward calculations and assessment against current reward factors.

g. Improvement Measure Hold Harmless (§§ 422.166(g)(1) and 423.186(g)(1)) (pg. 181)

i. Indicates that CMS believes that the hold harmless provision for the highest rating is not needed for 4 and 4.5 star contracts because they still have the potential to increase scores across measures and thus their Star Ratings.

ii. In order to encourage continued improvement across all measures for contracts with 4 and 4.5 stars for their highest rating, CMS proposes to modify § 422.166 at paragraphs (g)(1)(i) and (ii) and § 423.186 at paragraphs (g)(1)(i) and (ii) to apply the improvement measure hold harmless provision to only contracts with 5 stars for their highest rating beginning with the 2026 Star Ratings.

h. Extreme and Uncontrollable Circumstances (§§ 422.166(i) and 423.186(i)) (pgs. 181-182)

i. Proposes to limit to the 2025 and earlier Star Ratings, application of the rule at §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) that excludes numeric values for affected contracts with 60 percent of their enrollees residing in FEMA designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance from cut point calculations and reward factor determinations.

ii. Beginning with the 2024 Star Ratings, measure scores that are extreme outliers will be removed through Tukey outlier deletion, a standard statistical method to remove extreme outliers, as codified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), prior to applying the clustering methodology to determine the cut points.

iii. Proposes to amend sections §§ 422.166(i)(9)(i), 422.166(i)(10)(i), 423.186(i)(7)(i), and 423.186(i)(8)(i) to remove the 60 percent rule beginning with the 2026 Star Ratings for non-CAHPS measures, including the Health Outcomes Survey (HOS) measures even though the measurement period is slightly different for these measures.

iv. Proposes to clarify in § 422.166(i)(3)(iv) the timing for HOS measure adjustments for extreme and uncontrollable circumstances (for measures derived from the HOS, the disaster policy adjustment is for three years after the extreme and uncontrollable circumstance).

i. Quality Bonus Payment Rules (§ 422.260) (pgs. 182-183)

i. Proposes to clarify in § 422.260(c)(3)(iii) some additional aspects of the administrative review process for appeals of QBP status determinations. These clarifications reflect how CMS has historically administered the appeals process (no changes to how the appeals process has previously been administered).

ii. Proposes to clarify at § 422.260(c)(3)(iii) that an administrative review cannot be requested based on data accuracy for the following data sources: HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder pricing files, data from the Medicare Beneficiary Database Suite of Systems, MARx system, and other Federal data sources.

iii. Proposes that MA organizations cannot appeal measures that are based on feedback or surveys that come directly from plan enrollees.

iv. Proposes to require the MA organization to prove by a preponderance of evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect and to add additional language at § 422.260(c)(2)(v) clarifying that the burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status.

v. Proposes additional language at § 422.260(c)(1)(i) to clarify that ratings can go up, stay the same, or go down based on an appeal of the QBP determination.

vi. Proposes to add language at § 422.260(d) to clarify that a reopening of a QBP determination to address a systemic calculation issue that impacts more than the MA organization that submitted an appeal would only be updated if it results in a higher QBP rating for other MA organizations that did not appeal (consistent with historical process).

j. Calculation of Star Ratings (§§ 422.166(a)(2)(i) and 423.186(a)(2)(i)) (pgs. 183-184)

i. CMS notes that it appears that the sentence in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) ("Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed.") was inadvertently removed from the codified regulation text. CMS proposes a technical amendment to fix this codification error from the May 2022 final rule.

ii. In addition, although the provision regarding application of the Tukey outlier deletion policy was originally at the end of paragraph (a)(2)(i) in each regulation, CMS also proposes a non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) since Tukey outlier deletion is applied prior to the other steps.

6. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy (pgs. 184 -222)

a. Contract Year Definition (§ 460.6) (pgs. 184-185)

i. CMS proposes to amend the definition of contract year at § 460.6 to state that a PACE organization's initial contract year may be 19 to 30 months, as determined by CMS, but in any event will end on December 31. Under the proposed contract year definition, although the duration of the initial contract year of the trial period would change, the initial contract year would continue to begin when the program agreement is signed and end on December 31 to ensure subsequent contract years follow the standard annual calendar year cycle. For PACE organizations with an initial contract year start date of January 1 through June 1, CMS would extend the initial contract year through the following year. Additionally, for PACE organizations with an initial contract year start date of July 1 through December 1, CMS would extend the initial contract year through the second succeeding year. This would allow CMS to continue adjusting the length of the initial contract year so that subsequent contract years align with the calendar year, but it would provide greater flexibility around scheduling the first trial period audit.

ii. CMS is soliciting comment on whether CMS should consider a different timeframe for the initial contract year. Specifically, we are seeking feedback on whether CMS should

consider defining the initial contract year as 25 to 36 months to allow organizations additional time to implement and operate a PACE program before undergoing their first audit.

b. Determining that a Substantially Incomplete Application is a Nonapplication (§§ 460.12 and 460.20) (pgs. 185-186)

i. Proposes to strengthen the PACE regulations at §§ 460.12(a) and (b) and 460.20(b), which pertain to application requirements, by further defining what constitutes a complete and valid application.

ii. Under this proposal, CMS would treat any PACE application that does not include a signed and dated State assurances document that includes accurate service area information and the physical address of the PACE center as incomplete and invalid and therefore not subject to review or reconsideration. Entities that submit an application without a complete and valid State assurances document would have their application withdrawn from HPMS. They would then have to wait until the next quarterly submission date to submit the application with the State assurances included. CMS proposes to add paragraph § 460.12(b)(3) to specify that any PACE application that does not include the proper State assurances documentation associated with the application would be considered incomplete and invalid.

iii. Proposes to amend § 460.12(a), which states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area (through a geographic service area expansion and/or addition of a new center site) must submit a complete application to CMS "in the form and manner specified by CMS" by adding a parenthetical with the words "including timeframes for submission" after "manner", in order to make clear that CMS will only accept applications that are submitted within the timeframes established by CMS.

iv. Proposes to establish at § 460.20(c) that any application that, upon submission, is determined to be incomplete under proposed § 460.12(b)(3) because it does not include a signed and dated State assurances document with accurate service area information and the physical address of the PACE center, as applicable, would be withdrawn by CMS, and the applicant would be notified accordingly. Proposed § 460.20(b)(1) would further specify that the applicant would not be entitled to a hearing if the application is withdrawn based on that determination. Without the necessary evidence of support for the application by the SAA, the application would not be valid and therefore not subject to reconsideration. (Consistent with MA and Part D policy)

v. Proposes to establish at § 460.12(a)(2) that an individual authorized to act for an entity that seeks to become a PACE organization (initial PACE applicant) is required to submit a separate Part D application that complies with the applicable requirements under Part 423 Subpart K. Existing PACE organizations seeking to expand their service area are not required to complete a Part D application. Therefore, consistent with existing practice, CMS is not proposing to establish Part D application requirements for PACE organizations seeking to expand their existing service area.

vi. Proposes to treat an initial PACE application that does not include responsive materials for one or more sections of its Part D application as substantially incomplete, and those applications would not be reviewed or subject to reconsideration. Should this proposal be finalized, if the Part D application associated with an initial PACE application is deemed substantially incomplete, that would render the PACE application incomplete and therefore not subject to review or reconsideration.

c. PACE Past Performance (§§ 460.18 and 460.19) (pgs. 186-191)

i. To effectively oversee the PACE program, CMS proposes to amend the PACE regulation at § 460.18 (CMS evaluation of applications) to incorporate an evaluation of past performance into the review of applications submitted by PACE organizations that seek to offer a PACE program or expand an approved program by adding a geographic service area and/or PACE center site or sites.

   A. CMS evaluation of past performance would be a criterion CMS would use to review a PACE organization's application. This would permit CMS to deny applications from PACE organizations based on the organization's past performance and would take into account any compliance letters received by an organization.

   B. Also proposes that CMS may deny a PACE application if the PACE organization's agreement was terminated or not renewed during the 38 months preceding the date the application was first submitted to CMS.

   C. This section models the PACE past performance proposal after the MA and Part D review regulations at 42 CFR Parts 422 and 423.

ii. Proposes, at § 460.18(c)(1)(i), to evaluate the following components of an applicant organization's past performance starting with the March 2024 quarterly application submission cycle:

   A. whether the organization was subject to an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40, even if the reasons for the sanction have been corrected and the sanction has been lifted;

   B. whether the organization failed to maintain fiscal soundness;

   C. whether the organization has filed for or is under State bankruptcy proceedings; and whether the organization has exceeded CMS' proposed 13-point threshold for compliance actions with respect to the PACE program agreement.

iii. Proposes that if any of the above circumstances applies to the applicant organization, CMS may deny its initial or expansion application and proposes to include the imposition of enrollment or payment sanctions under § 460.42 for one of the violations listed in § 460.40 as a reason for which CMS may deny a PACE application.

iv. Proposes to specify at new § 460.19(c) the types of compliance actions CMS currently issues:

   A. NONC – Notice of Non-Compliance (1 point)

      1. May be issued for any failure to comply with the requirements of the PACE organization's current or prior PACE program agreement.

      2. CMS typically uses NONCs to document small or isolated problems. They are the lowest form of a compliance action issued by CMS.

      3. Least egregious failures such as a first-time offense, a failure that affects only a small number/percentage of participants, or issues that have no participant impact.

   B. WL - Warning Letter (3 points)

      1. Issued for serious and/or continued noncompliance with the requirements of the PACE organization's current or prior program agreement.

      2. CMS typically issues WLs as an intermediate level of compliance action,

between a NONC and a CAP.

3. They are issued either when an organization has already received a NONC, yet the problem persists, or for a first offense for larger or more concerning problems, such as failure to provide medically necessary services.

4. Unlike NONCs, these letters contain warning language about the potential consequences to the organization should the non-compliant performance continue.

5. Similar to CAPs, WLs are issued for more egregious instances of noncompliance or continued non-compliance. However, they are issued when the egregiousness or continued non-compliance may not warrant a CAP.

C. CAP - Corrective Action Plan (6 points)

1. Most serious type of compliance action and may be issued for particularly egregious or continued noncompliance.

2. CMS may determine that the PACE organization has repeated, not corrected, or has a new deficiency which substantially impacts beneficiaries. In these cases, CMS requires the PACE organization to implement a CAP.

v. Proposes to put in regulations the factors CMS currently uses when determining whether to issue a compliance action and what level of compliance action to issue. CMS considers the following factors:

A. The nature of the conduct,

B. the degree of culpability of the PACE organization,

C. the actual or potential adverse effect on participants which resulted or could have resulted from the conduct of the PACE organization,

D. the history of prior offenses by the PACE organization or PACE organization's contractors or subcontractors,

E. whether the non-compliance was self-reported, and

F. other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

vi. Proposes at § 460.18(c)(1)(ii) that CMS could also deny an application from an organization that does not hold a PACE program agreement at the time of the submission, if the applicant's parent organization or another subsidiary of the same parent organization meets the past performance criteria for denial proposed in § 460.18(c)(1)(i). Specifically, if an initial applicant is a legal entity under a parent organization that has a PACE program agreement, or if there are other organizations under the same parent that have a PACE program agreement, and the parent's PACE application or the other related organizations' PACE applications would be denied based on any of the factors proposed in § 460.18(c)(1)(i), CMS would also deny the new entity's application based on the past performance of other members of its corporate family.

vii. Proposes one exception to allow that a PACE organization that acquires an organization

that would have an application denied based on any of the factors in § 460.18(c)(i) would have a 24 month "grace" period that would extend only to the acquiring parent organization. This means that the acquiring organization would still be able to enter into new agreements or expand its programs under other agreements for which there are no performance issues for 24 months following the acquisition.

viii. Proposes to add a new paragraph § 460.18(d) to provide CMS the explicit authority to consider prior termination history as part of the evaluation of an initial PACE or expansion application. if CMS has terminated a PACE organization's program agreement under § 460.50(a), or did not renew the program agreement, and that termination or non-renewal took effect within the 38 months prior to the submission of an application by the PACE organization, CMS would be able to deny the PACE organization's application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant satisfies all other application requirements.

d. Clarification of PACE Enforcement Authority for Civil Money Penalties and Intermediate Sanctions (§ 460.40(b)) (pgs. 191-192)

i. CMS proposes to revise § 460.40(b) by adding the following: "If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administrating agency has to determine that the circumstances in 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension.".(removes the requirement that PACE organizations have an opportunity to correct prior to imposing a CMP or suspensions of enrollment and/or payment)

e. Personnel Medical Clearance (§§ 460.64 and 460.71) (pgs. 192-195)

i. CMS notes that based on audit and oversight experience, they have found that PACE organizations have many varied interpretations of what it means for staff to be "medically cleared for communicable disease." As a result, PACE organizations do not implement consistent methods for assessing or detecting communicable diseases.

ii. Proposes several modifications to the personnel medical clearance requirement at § 460.64(a)(5). Currently, the language states that staff must "be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact." CMS proposes to separate the requirement to be medically cleared for communicable diseases from the requirement to have all immunizations up to date. CMS proposes to create a new paragraph (a)(6) that would specify that each member of the PACE organization's staff (employee or contractor) who has direct contact with participants must have all immunizations up to date before engaging in direct participant contact. Proposed paragraph (a)(6) would include language specifying that, at a minimum, vaccinations identified in § 460.74 must be up to date.

iii. CMS is considering limiting the required vaccinations for PACE staff with direct participant contact to (in addition to the Covid-19 vaccine) the Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B and solicits comment on whether any specific vaccinations other than the COVID-19 vaccination should be required for each member of a PACE organization's staff (employee or contractor) that has direct participant contact.

iv. CMS proposes to require that each member of a PACE organization's staff (employee or contractor) who has direct participant contact be medically cleared of communicable diseases both before engaging in direct participant contact and on an annual basis.

v. CMS proposes adding requirements to define what would constitute an acceptable medical clearance process, which will be for each individual with direct participant contact

on a PACE organization's staff (employee or contractor) undergo a physical examination by a provider acting within the scope of their authority to practice, including an initial screen for TB.

vi. CMS proposes that, as an alternative to medically clearing all staff with direct participant contact for communicable diseases based on a physical examination, the PACE organization could opt to conduct an individual risk assessment as allowed under proposed § 460.64(a)(5)(iii). If the results of the risk assessment indicate the individual does not require a physical examination in order to be medically cleared, then a physical examination would not be required. (Includes minimum requirements for risk assessment)

f. PACE Contracted Services (§ 460.70) (pgs. 195-197)

i. Proposes to add back into the regulation the list of medical specialty services identified in the original PACE protocol that the PACE organizations must ensure access to as a minimum requirement. Specifically, CMS proposes to amend by adding language to § 460.70(a)(1) that specifies that PACE organizations are required to execute and maintain a contract with the following medical specialties: anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, general surgery, thoracic and vascular surgery, and urology.

ii. CMS notes the above specialty list as a minimum requirement for all PACE organizations; and that each PACE organizations should consider the needs of its participants to determine what additional medical specialists may be necessary for its network to be sufficient. CMS solicits comment on the addition of more specialties to the list.

iii. Proposes at new § 460.70(a)(2) to require a PACE organization to execute these contracts with specialists prior to enrollment of participants, and to require the PACE organization to maintain such contracts on an ongoing basis to ensure participants receive appropriate and timely access to all necessary care and services.

iv. Establishes that a PACE organization must make reasonable and timely attempts to contract with medical specialists.

v. Proposes to establish at § 460.70(a)(3)(i) that if at any time a PACE organization is unable to directly contract with a specific entity to provide specialist services to participants, the PACE organization must still ensure ongoing access to necessary care and services that would otherwise be provided to participants by a contracted specialist, and that the participant's needs are met, through a different mechanism which may include hospitalization.

vi. Establishes the expectation that an organization promptly report any contracting problems to CMS and the State Administering Agency (SAA), and include information on what attempts were made, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary services. This reporting may be initiated by the PACE organization when reasonable attempts to contract have been made and were unsuccessful; or it may be done in response to CMS or the SAA inquiring as to the status of the contracts.

vii. Proposed § 460.70(a)(4) would exempt a PACE organization from the contract requirements in § 460.70(a)(1) and (2) with respect to a particular medical specialty if a

PACE organization employs one or more individuals prior to contracting who are legally authorized and, if applicable, board certified, in the particular medical specialty.

g. Timeframes for Coordinating Necessary Care (§ 460.98(b)(4) and (c)) (pgs. 197-200)

i. Proposes at new § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after the primary care provider orders the medication. This timeframe would not require the medication to be delivered to the participant within that 24 hours, unless the participant's condition required delivery in that timeframe.

ii. Proposes to establish at new § 460.98(c)(2) the requirement that PACE organizations arrange or schedule the delivery of IDT approved services, other than medications, as identified in proposed § 460.98(c)(2)(i), as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or a member of the IDT first approves the service, except as identified in proposed § 460.98(c)(3). This requirement would apply to all services that are not medications. The 7-day timeframe begins once approval is made by the IDT or a member of the IDT, and should be considered a maximum, based on participant's health and medical needs.

iii. Proposes at § 460.98(c)(2)(i)(A) through (D) to define which services are included in the definition of interdisciplinary team approved services. This includes services approved by the full IDT or approved by any member of the IDT and would be subject to the 7 day timeframe. The timeframe begins when the IDT or a member of the IDT first approves a service.

iv. Propose at the new § 460.98(c)(3) to exclude routine or preventative services from the timeframe to requirement in § 460.98(c)(2) when certain requirements are met. Defines three requirements would all need to be met in order for a PACE organization to be exempt from the timeframe"

A. The PACE organization must document that they were unable to schedule the appointment for the routine or preventative service due to circumstances beyond the control of the PACE organization.

B. The PACE organization is exempt from the timeframe as long the participant does not have a change in status that requires the service to be provided more quickly. If the participant does experience a change in status that would warrant a faster appointment, the exception would no longer apply, and the PACE organization would be expected to schedule the service as necessary; and

C. The PACE organization may be exempt from the timeframes to arrange a service if the PACE organization provides the service as expeditiously as the participant's condition requires.

h. Care Coordination (§ 460.102) (pgs. 200-203)

i. Proposes to modify § 460.102(d)(1) to specify that the IDT is responsible for all activities as described at § 460.102(d)(1)(i) through § 460.102(d)(1)(iv) for each participant. The proposed regulation would include the words "for each participant" to emphasize that these responsibilities are not general requirements the IDT must fulfill, but rather specific responsibilities the IDT must fulfill for each participant.

ii. Proposes to modify the requirement at § 460.102(d)(1)(i) to include only the IDT's responsibility for the initial assessment, periodic assessment, and plan of care and to relocate the requirement pertaining to the IDT's responsibility to coordinate 24-hour care delivery to new § 460.102(d)(ii) as this responsibility to coordinate 24-hour care delivery

is a separate and distinct requirement from the requirements to conduct assessments and create or revise a plan of care.

iii. Proposes to modify the language of § 460.102(d)(1)(ii) and to add 5 paragraphs at § 460.102(d)(1)(ii)(A) through (E) to further specify what coordination of 24-hour care delivery involves by defining what actions CMS considers care coordination to include.

iv. Proposes at new § 460.102(d)(1)(ii) to require that the IDT coordinate and implement 24-hour care delivery that meets participant needs across all care settings. Added language into this requirement about meeting the participant's needs across all care settings in order to clarify the scope of the IDT's care coordination for all participants, including, but not limited to, participants residing in long-term care facilities.

v. Proposes at § 460.102(d)(1)(ii)(A) that the IDT is responsible for ordering, approving, or authorizing all necessary care in order to clarify CMS expectations regarding one aspect of the IDT care coordination responsibilities.

vi. Proposes at § 460.102(d)(1)(ii)(B) to establish that the IDT is responsible for communicating all necessary care and relevant instructions for care. As a part of coordinating care, the IDT must ensure that it communicates the necessary care and instructions to those individuals that need to know, for example, the individuals who will schedule, arrange, or provide the care and services.

vii. Proposes at § 460.102(d)(1)(ii)(D) to establish that the IDT is responsible for monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs.

viii. Proposes to specify at § 460.102(d)(1)(ii)(E) that the IDT is responsible for promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant.

ix. Proposes to add § 460.102(d)(1)(iv) to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists.

x. PACE organizations must continue to provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs. In order to meet the participant's needs, the IDT may need to review and act on recommendations sooner than the timeframes proposed in § 460.102(d)(1)(iv). Nothing in § 460.102(d)(1)(iv) would require the IDT to approve all recommendations; however, CMS would expect that the IDT review, assess, and act on the recommendation.

xi. Proposes at § 460.102(d)(1)(iv)(A) to establish that the appropriate member(s) of the IDT must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs within 24 hours from the time of the participant's discharge.

xii. Proposes to require at § 460.102(d)(1)(iv)(B) that the appropriate member(s) of the IDT must review all recommendations from other employees and contractors and make a determination with respect to whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 5 calendar days from the date the recommendation was made.

A. The proposed 5-day timeframe would represent the maximum amount of time a

PACE organization would have to determine whether a recommended service is necessary, and CMS would expect the IDT to consider the participant's condition in determining whether it is necessary to make a determination sooner than 5 days after the recommendation is made. Additionally, CMS proposes that the timeframe would begin when the recommendation is made, not when the recommendation is received by the IDT.

xiii. Proposes to establish at § 460.102(d)(1)(iv)(C) that, if recommendations are authorized or approved by the IDT or a member of the IDT, the services must be promptly arranged and furnished under § 460.98(c), as proposed.

A. If a hospital, at the time of discharge, makes a recommendation for a medication, the appropriate members of the IDT would have 24 hours to act on the recommendation, and if approved and ordered by the PCP, another 24 hours to arrange for the medication to be dispensed under proposed § 460.98(c)(1).

B. If a specialist recommends a medication, then the IDT would have 5 calendar days to make a determination with respect to the recommendation, and if it is approved and ordered, 24 hours to arrange for the medication to be dispensed.

C. If a recommendation is made from a contractor such as a medical specialist for a service that is not a medication, the IDT would have 5 calendar days to consider and act on the recommendation, and then, if approved or authorized, the PACE organization would have 7 calendar days to arrange or schedule the approved or authorized service.

D. The timeframe to schedule the service would begin the day the IDT or a member of the IDT approves or authorizes the recommendation.

i. Plan of Care (§ 460.106) (pgs. 203-210)

i. Proposes to modify the requirement in § 460.106(a) to require that the members of the IDT specified in § 460.102(b) must develop, evaluate, and if necessary, revise a person centered plan of care for each participant. This is consistent with the requirement at § 460.104(b) that states that within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT. Additionally, the IDT is required to reevaluate the plan of care on a semi-annual basis at the current § 460.106(d); however, CMS is proposing to remove that requirement as the proposal at § 460.106(a) would cover the role of the IDT in both the initial care plan development and also the subsequent reviews and reevaluations of the care plan. CMS also proposes to add language into § 460.106(a) that would require each plan of care to take into consideration the most current assessment findings and identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being.

ii. Proposes to add a new section, § 460.106(b), which would define the specific timeframes for developing, evaluating, and revising care plans. For initial care plans, CMS intends to maintain the requirement for the IDT to finalize the development of the initial plan of care within 30 calendar days of the participant's enrollment that is located at current § 460.106(a) but moves the requirement to new section § 460.106(b)(1). CMS proposes at § 460.106(b)(2) to require that the IDT must complete a reevaluation of, and if necessary, revisions to each participant's plan of care at least once every 180 calendar days.

iii. Proposes at § 460.106(b)(3)(i) that the IDT must complete a reevaluation, and if necessary, revisions of the plan of care within 14 calendar days after the PACE

organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status or more expeditiously if the participant's condition requires. Also proposing to modify § 460.104(e) to emphasize that all required assessments must be completed prior to the plan of care being revised. Therefore, this 14-calendar day timeframe would include both the required assessments under § 460.104(d)(1) and the process of revising the plan of care under § 460.106.

iv. Proposes to specify at § 460.106(b)(3)(i) that the 14-calendar day timeframe starts when the PACE organization determines, or should have determined, that a change in the participant's condition occurs. The requirement as proposed would state that for purposes of this section, a "change in participant status" means a major decline or improvement in the participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status and requires IDT review or revision of the care plan, or both.

v. Proposes at § 460.106(b)(3)(ii) that if a participant is hospitalized within 14 calendar days of the change in participant status, the IDT must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital.

vi. Proposes at § 460.106(c) to make certain modifications related to the content of a plan of care. in addition to proposing to move the content of plan of care requirements from § 460.106(b) to § 460.106(c), CMS proposes to add language to the section to create minimum requirements for what each plan of care must include.

A. Plan of care currently must include the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.

B. Plan of care should address all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring.

C. Proposes in PACE to limit what diseases must be included in the plan of care to those that are chronic and require treatment or routine monitoring.

D. Proposes to specify at § 460.106(c)(1)(i), (ii), and (iii) that the PACE participant's plan of care must address the participant's vision, hearing and dentition needs.

E. Propose at § 460.106(c)(1)(iv) that a plan of care must address the participant's skin integrity.

F. Propose at § 460.106(c)(1)(v) that the participant's plan of care must address the participant's mobility. And at § 460.106(c)(1)(vi) that the participant's plan of care must address the participant's physical functioning (including activities of daily living).

G. Proposes at § 460.106(c)(1)(vii) that the plan of care must address the participant's pain management needs.

H. Proposes to require at § 460.106(c)(1)(viii) that the plan of care address the participant's nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs.

I. Proposes at § 460.106(c)(1)(ix) to establish the requirement that the plan of care address the participant's ability to live safely in the community, including the safety of their home environment. The IDT must assess the participant's environment and

living situation for potential factors that may make it not safe for the participant.

J. Proposes at § 460.106(c)(1)(x) that the plan of care must address the participant's home care needs.

K. Proposes to establish at § 460.106(c)(1)(xi) that the participant's center attendance must be included in the plan of care.

L. Proposes at § 460.106(c)(1)(xii) to require that a participant's transportation needs be incorporated into the plan of care.

M. Proposes to require at § 460.106(c)(1)(xiii) that a participant's communication needs (including any identified language barriers) be incorporated into the plan of care.

N. Proposes at § 460.106(c)(2) to require that the plan of care must identify each intervention (the care or service) needed to meet the participant's medical, physical, emotional, and social needs.

O. Propose to include at § 460.106(c)(2) an exception to the interventions that need to be included in the plan of care; specifically, proposed § 460.106(c)(2) would provide that the plan of care does not need to identify the medications needed to meet a participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record.

P. Proposes at § 460.106(c)(4) to specify that the plan of care must identify how each service will be implemented, including a timeframe for implementation. As part of the plan of care process, the IDT should determine the parameters of a service, specifically how it will be provided to the participant in order to meet their needs.

Q. Proposes at § 460.106(c)(5) to require that the plan of care must identify a measurable goal for each intervention.

R. Proposes at § 460.106(c)(6) to require that the care plan identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified.

S. Proposes at § 460.106(c)(7) to require that the plan of care must identify the participant's preferences and goals of care.

vii. Currently, § 460.106(c)(1) requires the team to implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or CMS contractors. CMS proposes to move this language to § 460.106(d)(1) and to modify it to read that the IDT must continuously implement, coordinate, and monitor the plan of care, regardless of whether the services are furnished by PACE employees or contractors, across all care settings.

viii. Proposes to add § 460.106(d)(3) to state that all services must be arranged and provided in accordance with the § 460.98(c) plan of care.

ix. Propose at § 460.106(e)(1) to modify language to state that the IDT must develop, evaluate, and revise each plan of care in collaboration with the participant or caregiver, or both" to refer to "each" plan of care in order to emphasize that this collaboration must be performed for every new plan of care, including the initial, semi-annual, and a revised plan of care as a result of a change in status.

x. Proposes at § 460.106(e)(2) that the IDT must review and discuss each plan of care with the participant and/or caregiver before the plan of care is completed to ensure that there is agreement with the plan of care and the participant's concerns are addressed.

xi. Proposes to modify the language in § 460.106(f) to state that the team must establish and implement a process to document and maintain records related to all requirements for the plan of care in the participant's medical record and ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

xii. Proposes to remove most of the language currently in section § 460.104(e) and add the requirement that when the IDT conducts semiannual or unscheduled reassessments, the IDT must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments. This change is made in order to eliminate any unnecessary duplication and ensure there is no confusion as it relates to care plans.

j. Specific Rights to Which a Participant is Entitled (§ 460.112) (pgs. 210-213)

i. CMS is proposing to amend § 460.112 to incorporate the following participant rights:

A. the right to appropriate and timely treatment for health conditions including the right to receive all care and services needed to improve or maintain the participant's health condition and to attain the highest practicable physical, emotional and social well-being;

B. the right to have the PACE organization explain all treatment options;

C. the right to be fully informed, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services;

D. the right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services; and

E. the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121.

F. the right to have all information regarding PACE services and treatment options explained in a culturally competent manner.

G. the right to have all information in this section shared with their designated representative

H. the right to be fully informed, in writing, of several factors before the PACE organization implements palliative care, comfort care, or end-of-life care. We propose that the written notification to participants must explain four different aspects of the treatment options:

1. the written notification must include a description of the palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving to meet their individual needs.

2. explain, in writing, to participants or their designated representative whether palliative care, comfort care, or end-of life care services (as applicable) will be provided in addition to or in lieu of the care the participant is currently receiving.

3. require PACE organizations to identify all services that would be impacted if the participant and/or their designated representative elects to initiate palliative care, comfort care, or end-of-life care. PACE organizations would be required to provide a detailed explanation of how specific services would be impacted by the addition of or transition

to palliative care, comfort care, or end-of-life care.

4. Proposed § 460.112(c)(5)(iv) would state that the participant has the right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason either verbally or in writing. We also propose to require PACE organizations to explain this right to participants both orally and in writing.

I. Proposes to add additional specificity around the right to be informed of the consequences of the decisions and the obligation it creates for PACE organizations by modifying the regulatory language to refer to the participant's right to "be informed of the consequences their decisions may have on their health and/or psychosocial status." CMS believes this proposed revision would emphasize that the participant should be made aware of how their decision to refuse care may impact their health and/or psychosocial status.

J. At § 460.112(e)(2)(i), proposes to establish that the PACE organization must fully explain the applicable treatment options to the participant prior to initiating palliative care, comfort care, or end-of-life care services. This proposal would require the PACE organization to explain to the participant what these terms mean, and how choosing one of those options would impact the participant's health.

K. Proposes at § 460.112(e)(2)(ii) to require that the PACE organization provide the participant with written information about their treatment options in accordance with § 460.112(c)(5).

L. Proposes to add paragraphs (e)(2)(i) and (e)(2)(ii) as separate provisions because the organization should be responsible both for providing the written notification outlined in § 460.112(c)(5), and actually explaining the treatment options in a way that is understandable to the participant.

M. Proposes at § 460.112(e)(2)(iii) that the PACE organization obtain written consent from the participant or their designated representative to change a treatment plan to include palliative care, comfort care, or end of life care.

k. Grievance Process (§ 460.120) (pgs., 213-219)

i. Proposes to modify the requirement to state that each PACE organization must have formal written procedures to promptly identify, document, investigate and resolve all medical and nonmedical grievances in accordance with the requirements in this part.

ii. Proposes to add to § 460.120 a new paragraph (b), which would define a grievance in PACE as a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested; and further that a grievance may be between a participant and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant. Stresses that a grievance must be identified and processed if it satisfies the definition, regardless of whether remedial action is requested.

iii. Solicits comment on whether CMS should modify the PACE grievance definition to more closely resemble the definition of grievances in MA at § 422.561. Specifically, solicits comment on whether we should consider use of the following definition for PACE grievances: A grievance means any complaint or dispute expressing dissatisfaction with any aspect of the PACE organization's or it's contractors' operations, activities, or behavior, regardless of whether remedial action is requested.

iv. Adds new paragraphs (c)(1), (c)(2), and (c)(3) to § 460.120, which would set forth

requirements for the grievance process notification and solicits comment on whether the other individuals should receive the grievance process notification, in addition to the participant, upon the participant's enrollment and annually thereafter. Specifically, CMS is soliciting comment on whether the other individuals specified in § 460.120(d) should receive the grievance process notification, or at a minimum, whether the participant's designated representative should receive the notification in addition to the participant.

v. Proposes at § 460.120(c)(1) that the grievance process notification must include information on the right of the participant or other individual specified in § 460.120(d) to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal.

vi. Proposes at § 460.120(c)(2) that the grievance process notification must inform participants that a Medicare participant as defined in § 460.6 or other individual specified in §460.120(d) acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services, consistent with section 1154(a)(14) of the Act.

vii. Proposes at § 460.120(c)(3) to require that the grievance process notification include the grievance definition at § 460.120(b) and provide information on all grievance processing requirements in paragraphs (d) through (k) of § 460.120.

viii. Proposes to amend the list of individuals who can submit a grievance to include the participant's caregiver. (Current § 460.120(a) provides that grievances can be submitted by participants, family members or their representatives.)

ix. Adds rules around the submission of grievances in new paragraph § 460.120(e).

A. Proposed § 460.120(e)(1) would provide that any individual permitted to file a grievance with a PACE organization under § 460.120(d) may do so either orally or in writing.

B. Proposed § 460.120(e)(2) would establish that the PACE organization may not require a written grievance to be submitted on a specific form.

C. Proposed § 460.120(e)(3) would provide that a grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants.

D. Proposes new § 460.120(f) to establish the requirement that the PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known.

x. Proposes at § 460.120(g)(1) that the PACE organization must take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance.

A. Propose to adopt a modified version of the requirement in the MA regulations, which would specify that the 30-day timeframe is the maximum amount of time the PACE organization has to resolve the grievance, as opposed to the maximum amount of time to notify the participant. Proposed § 460.120(g) would maintain the language regarding ensuring that this timeframe is a maximum length of time, and that organizations may need to resolve grievances more quickly if the participant's case requires.

xi. Proposes at § 460.120(g)(2) that the PACE organization must notify the individual who

submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than three calendar days after the date the PACE organization resolves the grievance in accordance with § 460.120(g)(1).

xii. Proposed § 460.120(h) would establish requirements for the processing of expedited grievances.

A. Propose to require that the PACE organization must resolve and notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 24 hours after the time the PACE organization receives the oral or written grievance if the nature of the grievance could have an imminent and significant impact on the health or safety of the participant.

xiii. Proposes at new § 460.120(i) to create grievance resolution notification requirements for how the PACE organization must inform the individual who submitted the grievance of the resolution of that grievance.

A. Proposes at § 460.120(i)(1) that the PACE organization may inform the individual either orally or in writing, based on the individual's preference for notification, except for grievances identified in § 460.120(i)(3).

B. Proposes to establish at § 460.120(i)(2) that oral or written notification of grievance resolutions must include a minimum of three requirements.

1. that the notification must include a summary statement of the participant's grievance including all distinct issues.

2. that for each distinct issue that requires an investigation, the notification must include the steps taken to investigate the issue and a summary of the pertinent findings or conclusions regarding the concerns for each issue.

3. that for a grievance that requires corrective action, the grievance resolution notification must include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur.

C. Proposed § 460.120(i)(3) would set forth requirements related to how PACE organizations must provide notification when the complaint relates to a Medicare quality of care issue. Specifically, propose at § 460.120(i)(3) that, when a grievance relates to a Medicare quality of care issue, the PACE organization must provide a written grievance resolution notification that describes the right of a Medicare participant or other individual specified in § 460.120(d) acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. The only exception to this requirement to provide a written resolution notice would be when the submitter specifically requests not to receive notification as specified in proposed §460.120(i)(4). Also propose to specify that for any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint.

D. Proposes to establish at new § 460.120(i)(4) that the PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive notification of the grievance resolution, and the PACE organization has documented this request in writing. PACE participants must have an option to request not to receive any further communication or notification of the grievance resolution following their initial complaint submission and the PACE organization must document this in writing.

xiv. Adds a new paragraph § 460.120(k) that would redesignate and modify the requirement that is currently included at § 460.120(c)(4). Proposes that the PACE organization must develop and implement procedures to ensure that they maintain the confidentiality of a grievance, including protecting the identity of any individuals involved in the grievance from other employees and contractors when appropriate.

xv. Adds a new paragraph at § 460.120(l) that aligns with the record keeping requirements for service determination requests. Proposed § 460.120(l) would require that a PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of § 460.120(k), must be available to the IDT to ensure that all members remain alert to pertinent participant information.

xvi. Redesignated § 460.120(m), as revised would state that the PACE organization must aggregate and analyze the information collected under paragraph (l) of this section for purposes of its internal quality improvement program. CMS notes that this requirement applies to all grievances; oral or written, including anonymous grievances.

l. Service Determination Request (§ 460.121) (pg. 219)

i. Proposes to revise the requirement in § 460.121(i)(2) to allow the IDT to provide notification either orally or in writing to the participant or their designated representative when the IDT extends the timeframe for a service determination request, as permitted under § 460.121(i)(1). CMS expects that PACE organizations would document the content of oral notifications of service determination request extensions in accordance with § 460.121(m).

m. Participant Notification Requirement for PACE Organizations with Performance Issues or Compliance Deficiencies (§ 460.198) (pgs. 219-220)

i. Effective beginning in CY 2024, CMS proposes to amend the regulations at Part 460 by adding § 460.198, which would require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS. As in the MA and Part D programs, CMS anticipates they would invoke the disclosure requirement when they become aware that a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or requires immediate correction, and where they believe PACE participants and potential PACE participants should be specifically notified.

n. PACE Maintenance of Records (§§ 460.200 and 460.210) (pgs. 220-222)

i. Proposes to amend § 460.200(d)(2) to require that a PACE organization must maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety, including, but not limited to, the following:

A. communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's care, health, or safety; and

B. communications from an advocacy or governmental agency, such as Adult Protective Services.

ii. At § 460.210(b)(6), proposes to replace the current language with a new requirement that states that original documentation or an unaltered electronic copy, of any written

communication as described in § 460.200(d)(2), must be maintained in the participant's medical record unless the following requirements are met:

A. the medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication,

B. original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and

C. original documentation of the communication is available to CMS and the SAA upon request.

iii. This proposal would continue to require PACE organizations to ensure that these important communications relating to the care, health, or safety of a participant are included in the medical record, but it would allow PACE organizations operational flexibility on how these communications are included. PACE organizations would be permitted, under this proposal, to summarize the information in the medical record, as long as the summary is accurate and thorough, and the original documentation of the communication is maintained outside the medical record and is accessible by the PACE organization's employees and contractors as needed, and available to CMS and the SAA upon request.

o. PACE Participant Health Outcomes Data (§ 460.202) (pg. 222)

i. Since the participant health outcomes data that PACE organizations must report to CMS and the SAA are specified and routinely updated through the PRA process which requires CMS to publish and solicit comments on these data, CMS proposes to amend paragraph (b) of § 460.202 by striking the final sentence, which states, "The items collected are specified in the PACE program agreement." This change would eliminate confusion regarding where the data collection requirements may be found. The PACE program agreement would still include a statement of the data collected, as required by § 460.32(a)(11), but it would not include the level of specificity regarding the data collection that is included in the CMS PRA information collection request approved under OMB control number 0938-1264.

7. Collection of Information Requirements (pgs. 222-298)

i. Addresses the solicitation of comments under Paperwork Reduction Act of 1995 (PRA)

ii. Outlines financial impact information for all proposals