Summary of CY2021 Proposed Medicare Advantage and Part D Policy & Technical Changes

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Overview

On February 5, 2020, the Centers for Medicare and Medicaid Services ("CMS") released a proposed rule outlining **Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and the Programs of All-Inclusive Care for the Elderly.**

In the wide-ranging 895-page document, CMS details proposed policy updates primarily focused on implementing certain sections of other federal laws related to the Medicare Advantage Part C and Part D programs.

In this summary we provide highlights of the proposed policy updates as well as a more detailed outline that follows the sequence of the CMS document. Our summary emphasizes the material that Wakely views as most relevant to product design and MA/PD bid preparation, and should not be viewed as all-inclusive. It has been written for those who are familiar with MA/PD programs and methods.

The proposed policy and technical change document in its entirety can be found here:

https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf

The CMS Fact Sheet summarizing the proposed policy changes can be found here:

https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-and-2022-medicare-advantage-and-part-d-proposed-rule-cms-4190-p-1

Comments to the proposed rule are due April 6, 2020.

Executive Summary

From a payer perspective, the Proposed Rule clarifies or introduces several proposed policy changes that will impact Medicare Advantage Organizations' (MAOs) business.

The most impactful provisions of the Proposed Rule are outlined below.

- ESRD beneficiaries will be allowed to proactively enroll in Medicare Advantage (MA) plans beginning January 1, 2021. Previously, these beneficiaries were generally limited to enroll in MA plans only if the ESRD designation occurred after enrollment.

- Beginning January 1, 2021, MA-PD plans and PDPs will be allowed to add an additional "preferred specialty tier" to their formularies. Given bid submission deadlines and the time needed to finalize this provision, it is questionable whether this provision can be incorporated by plans prior to the June 1, 2020 bid submission deadline.

- Kidney acquisition costs will be covered under fee-for-service Medicare, and will not be covered by MA plans. As a result, these costs will be removed from the Part C benchmark calculations, which materially reduces benchmarks for many counties.

- "Look-alike" Dual Special Needs Plans will be disallowed beginning January 1, 2022 if certain dual enrollment thresholds are breached. While this provision begins in 2022, it will put pressure on MAOs offering these designs to modify or eliminate them in their 2021 offerings.

- Targeted changes are proposed to Star Rating measures that put more weight on patient experience and complaint measures as well as reduce the influence of outliers on measure calculations.

- Numerous changes are proposed related to Part D, including required implementation of a Real Time Benefit Tool, and mandatory drug management programs.

- Clarification and codification of previously released rules related to flexible benefits (special supplemental benefits for the chronically ill, uniformity requirements, and primarily health related) are included in the Rule.

- Network adequacy requirements are strengthened for Cost plans and relaxed for rural areas and for plans using Telehealth providers.

- Modification to Medicare Advantage minimum loss ratio formulas are proposal, including expanding the definition of "incurred claims" to include all services that meet the "primarily health related standard" covered under the plan benefit package, including those that may not have been furnished by a provider, clarifying credibility definitions, and applying a "deductible factor" for MSA plans.

The remainder of this summary provides highlights of the sections in the Proposed Rule in the same order as presented in the Rule.

Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

1. Special Supplemental Benefits for the Chronically Ill (SSBCI)

- There is a new category of supplemental benefits intended to enable MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for the chronically ill population.
- These benefits must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee, but they do not have to be primarily health related. Examples include:
    a. Meals (beyond a limited basis), food and produce, transportation for non-medical needs, pest control, and indoor air quality. Several other examples listed.
- Plans may define "chronically ill enrollee" to limit eligibility for these additional supplemental benefits.
- CMS waives the uniformity requirements in connection with this benefit category for eligible chronically ill enrollees.
- A chronically ill enrollee is defined as
    a. having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
    b. having a high risk of hospitalization or other adverse health outcomes; and
    c. requiring intensive care coordination.
- A panel of clinical advisors will prepare a list of conditions which MA plans can automatically assume meet the definition of "comorbid and medically complex," but they have the flexibility to consider chronic conditions not already on the preapproved list.
- Plans must document their decisions about an enrollee's eligibility for SSBCI.
- Plans must incur a non-zero direct non-administrative cost for the SSBCI.
- SSBCI can be in any of these forms:
    a. Reduced cost sharing for Medicare covered benefits (such as to improve utilization of high-value services that meet the definition of SSBCI);
    b. Reduced cost sharing for primarily health related supplemental benefits;
    c. Additional primarily health related supplemental benefits; or
    d. Additional non-primarily health related supplemental benefits.
- Plans may consider social determinants when determining an enrollee's eligibility for SSBCI, but social determinants may not be the sole consideration.
- Benefits do not necessarily need to be uniform across the entire population of chronically ill, but the plan must have written policies based on objective criteria.

2. Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

- The BBA modified requirements for CSNPs and the proposed rule extends the modified requirements to all SNP types (DSNP and ISNP also).
- There are two new requirements governing SNP enrollee care management:

a. The interdisciplinary team must include a team of providers with demonstrated expertise and training in treating individuals similar to the targeted population of the SNP.
b. The SNP must provide face-to-face encounters with enrollees on at least an annual basis.
    i. Interactive telehealth is acceptable
    ii. Enrollee may choose not to participate

- There are three new requirements governing SNP model of care submissions:
    a. As part of the mandatory model of care (MOC), the results of the initial assessment and annual reassessment required for each enrollee should be addressed in the individual's individualized care plan.
    b. As part of the annual evaluation and approval of the MOC, CMS will take into account whether the plan fulfilled the previous year's goals (as required under the model of care).
    c. CMS will establish a minimum benchmark for each element of the MOC and only approve a SNP's MOC if each element of the MOC meets such minimum benchmark.

3. Coverage Gap Discount Program Updates

- Proposes to amend the definition of "applicable drug" and the determination of coverage gap discount to reflect statutory provisions. Amends the following:
    a. Increases the coverage gap discount for applicable drugs from 50% to 70% of the negotiated price beginning in plan year 2019
    b. Revises the definition of an applicable drug to include biosimilar biological products beginning in plan year 2019.
    c. Clarifies the definition of "applicable discount". The applicable discount is 70% of the portion of the negotiated price of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available. Applies beginning in plan year 2019.

4. Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts

- For background, Section 3308 of the Affordable Care Act (ACA) amended section 1860D013(a) of the Act and imposed an income-related monthly adjustment amount for Medicare Part D for beneficiaries whose modified adjusted gross income exceeds the same income threshold amount tiers established under section 1839(i) of the Act with respect to Medicare Part B income-related monthly adjustment amount.
    a. Part D income tiers mirror those established for Part B.
    b. Dollar amounts within the income threshold tiers shall be adjusted annually based on the Consumer Price Index (CPI)
    c. Section 3402 of the ACA froze the income thresholds for 2011 through 2019 at the level established for 2010
    d. Section 3308 of the ACA requires CMS to provide the Social Security Administration (SSA) with the national base beneficiary premium amount used to calculate the Part D income tiers no later than September 15 of each year. In addition CMS must provide by October 15 of each year: the modified adjusted

gross income threshold ranges, the applicable percentages established for Part D income tiers, the corresponding monthly adjustment amounts and any other information SSA deems necessary to carry out the Part D income tiers.

e. Section 402 of MACRA revised the income thresholds
f. Section 53114 of BA of 2018 revised the modified adjusted gross income ranges such that beneficiaries with incomes >$500K (or $750K for joint filers) are required to pay 85% of program costs (increase from 80%)

- Rule proposes to revise the calculation for consistency with changes made by section 53114 of the BBA of 2018
    a. Removes the following language: "the product of the quotient obtained by dividing the applicable premium percentage that is based on the level of the Part D enrollee's modified adjusted gross income for CY reduced by 25.5 percent and the base beneficiary premium" and replaces it with the product of the standard base beneficiary premium and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent.

5. Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§422.514)

- There has been increased focus on providing integrated care for dually eligible individuals with the goal of improving care coordination, quality of care, and beneficiary satisfaction.
- The BBA of 2018 added new requirements for DSNPs, beginning in 2021.
    a. Minimum integration standards - A DSNP must be a (1) be a fully integrated dual eligible (FIDE) SNP; (2) be a highly integrated dual eligible (HIDE) SNP; or (3) have
    b. a contract with the state to notify the state of high-risk individuals' hospital and SNF admissions
    c. Medicaid coordination
    d. Unified appeals and grievances
- CMS has growing concern that DSNP look-alikes (non-SNPs with levels of dual eligible enrollment very similar to DSNPs and have benefits and cost sharing designed to attract only dually eligible individuals) allow MA organizations to circumvent enrollment restrictions and federal regulatory and state contracting requirements for D-SNPs and MMPs, undercutting efforts to lower costs and improve the quality of care.
- The Rule proposes that, beginning in 2022, CMS not enter into or renew a contract for a D-SNP look-alike. The definition of look-alike is a non-DSNP plan that either:
    i. Projects in its submitted bid that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX, or
    ii. Has actual enrollment, based on January of the current year, consisting of 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX.
- The proposed requirement would be limited to states where there is a D-SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as Medicare Medicaid Plans (MMPs).
- Exceptions for plans that are less than 1 year old or with less than 200 enrollees.
- There will be procedures established for transitioning enrollees from the D-SNP look alike plan to another plan or plans.

a. No election form needed
b. Members must be eligible for the plan they are being transitioned into (e.g. must reside in the service area)
c. Allowable to transition to a plan in another organization with same parent organization
d. The plan into which members are transitioned must have a combined Part C and D beneficiary premium of $0 after application of the premium subsidy for full subsidy eligible individuals.
e. Allowed to transition non-SNP to SNP, which has not been allowed previously.
f. The intent is for the transition process to take effect in time for D-SNP look-alikes operating in 2020 to utilize the transition process for enrollments to be effective January 1, 2021.

Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

1. Mandatory Drug Management Programs (DMP)

- SUPPORT Act made changes to the requirements for Part D DMP to enhance Part D sponsor's ability to reduce the abuse or misuse of opioid medications in their PD benefit plans.
  a. CMS is proposing to require Part D sponsors adopt DMPs by January 1, 2022 and to require inclusion of PD beneficiaries with a history of opioid-related overdose in sponsors' DMPs beginning in January 1, 2021.
  b. CMS is also proposing an additional category of exempt beneficiaries (sickle cell disease) from DMPs and proposing several technical clarifications to the DMP
  c. From 2011 to 2017 there was a 76% decrease in the number of Part D potential at-risk beneficiaries

2. Beneficiaries with History of Opioid-Related Overdose Including in DMPs

- Under SUPPORT Act, CMS is required to identify Part D Beneficiaries with a history of opioid-related overdoses as potential at-risk beneficiaries under a Part D plan's DMP.
  a. Proposing to define "history of opioid-related overdose" to mean a recent claim has been submitted that contains a principal diagnosis code reflecting an opioid overdose, and at least one recent PDE for an opioid dispensed to such beneficiary has been submitted**.**
     i. Rationale for the proposal is that a past overdose is the risk factor most predictive for another overdose or suicide-related event.
     ii. Propose using diagnoses that include both prescription and illicit opioid overdoses because an opioid overdose may result from prescription or illicit opioids alone or in combination, and the statute does not distinguish based on the type of opioid.
     iii. The proposed changes would be for a 12-month lookback period for claims related to overdose and 6-month lookback period for opioid PDE records.

iv. CMS identified 18,268 FFS beneficiaries under this proposal, and estimated about 4,500 new beneficiaries with opioid related overdose would be identified every quarter.

b. In this proposed rule, Part D sponsors with DMPs (which will be required in 2022) must conduct case management for each potential at-risk beneficiary identified by CMS which includes sending written information to the beneficiary's prescribers that the beneficiary met the clinical guidelines criteria and is a potential at-risk beneficiary.

3. Information of the Safe Disposal of Prescription Drugs

- CMS is proposing to revise the Disclosure Requirements to add a paragraph which would require MA plans that furnish in-home health risk assessment on or after January 1. 2021 to include both verbal and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. MA plans must do the following:
    a. Advise enrollee that unused medications should be disposed of as soon as possible
    b. Advise the enrollee that the US Drug Enforcement Administration allows unused prescription medications to be mailed back to pharmacies or other authorized sites using packages made available at such pharmacies or other authorized sites
    c. Advise the enrollee that the preferred method of disposing of controlled substances is to bring them to a drug take back site
    d. Identify drug take back sites that are within the enrollee's MA pan service area or that are nearest to the enrollee's residence
    e. Instruct the enrollee on safe disposal of medications that can be discarded in the household trash or safely flushed.
    f. If a drug can be safely disposed in enrollee's home, they should conceal or remove any personal information. If it can be discarded in the trash, enrollee should mix the drugs with an undesirable substance such as dirt or coffee grounds and place in a sealed container

4. Beneficiaries' Education on Opioid Risks and Alternative Treatments

- CMS proposes to amend regulations to reflect that Part D sponsors may provide educational information to a subset of enrollees, in lieu of providing it to all enrollees**.** Options include:
    a. Disclose opioid risk and alternate coverage information to all Part D enrollees (approx. 46.8M enrollees)
    b. Disclose opioid information to subset of beneficiaries suggested by the SUPPORT Act, which is enrollees who have been prescribed an opioid in the previous 2-year period (approx. 16.1M enrollees)
    c. Disclose the opioid information to the subset of all opioid users in the Part D program who had at least one opioid prescription in a year (approx. 11M enrollees)
    d. Disclose information to the subset of enrollees who have a greater than 7 days of continued opioid use (approx. 7.1M enrollees, or ~65% of all opioid users)

e. Disclose information to the subset of enrollees with greater than 30 days of continuous opioid use (approx. 3.8M enrollees, or ~35% of all opioid users)
f. Disclose information to subset of enrollees with greater than 90 days continuous opioid use, without more than a 7 day gap (approx. 2.7M enrollees, or ~24% of all opioid users)

- CMS proposes to revise the existing regulatory framework for the information that must be disclosed to include the opioid risk and alternative pain treatment coverage information that Part D sponsors must disseminate.

5. Eligibility for Medication Therapy Management Programs (MTMPs)

- CMS proposes to amend Part D Medication Therapy Management (MTM) program requirements to conform to the relevant SUPPORT Act provisions.
  a. The SUPPORT Act modified MTM program requirements for Medicare Part D plans beginning January 1, 2021, by expanding the population of beneficiaries who are targeted for MTM program enrollment ("targeted beneficiaries") to include at-risk beneficiaries (ARBs), and by adding a new service component requirement for all targeted beneficiaries.
  b. The Act also requires Part D plans to provide enrollees with information about the safe disposal of prescription drugs that are controlled substances.
  c. Under this proposal, Part D sponsors would be required to automatically enroll all at-risk beneficiaries in their MTM programs on an opt-out only basis. In addition, Part D sponsors would be required to offer each at-risk beneficiary enrolled in the MTM program the same minimum level of MTM services. (In addition to interventions for both beneficiaries and prescribers, sponsors must offer ARBs an annual comprehensive medication review.)
  d. CMS is seeking feedback on how sponsors' can best coordinate DMPs and MTMPs and effectively perform outreach to offer MTM services.
  e. CMS is also seeking comments on the type of information that CMS should use to monitor the impact of MTM services on ARBs, who will now be targeted for MTM services.
  f. This section also proposes to require that all MTM enrollees receive at least annually, information about safe disposal of prescription drugs that are controlled substances, take back programs, in-home disposal, and cost-effective means of safe disposal.

6. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries

- Proposing to codify the SUPPORT Act amendment which requires that if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, in whole or in part, the case shall be automatically forwarded to the independent outside entity contracted with the Secretary for review and resolution.
  a. To implement the changes required by the SUPPORT Act, CMS proposes revisions to the requirements for the content of the initial notice and the requirements for the second notice.
  b. Specifically, the notices should explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the independent review entity for review and resolution.

7. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures

- Proposals include changes to definitions for the following:
  a. Substantiated or Suspicious Activities of Fraud, Waste or Abuse
  b. Inappropriate Prescribing of Opioids
  c. Credible Allegation of Fraud
  d. Fraud Hotline Tip
- Proposals to Reporting:
  a. Vehicle for Reporting –CMS plans to utilize a module within the HPMS as the program integrity portal for information collection and dissemination.
  b. Type of Data to be Reported by Plans –
     i. Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, and
     ii. any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services or supplier, and other actions taken by the plan
  c. Includes the data elements to be reported in the portal
  d. Timing of Plan Sponsor's reporting –
     i. Sponsors are required to notify the Secretary 14 days prior to implementation of the payment suspension.
     ii. Includes additional quarterly reporting
  e. Requirements and Timing of CMS' Reports – CMS will provide quarterly reports containing information on fraud, waste and abuse schemes and trends in identifying suspicious activity to plans.

Implementation of Certain Provisions of the 21st Century Cures Act

1. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease ESRD Beneficiaries

- The 21st Century Cures Act removes the prohibition for beneficiaries with ESRD from enrolling in an MA Plan, effective January 1, 2021. Prior to 2021, ESRD beneficiaries could only be enrolled in an MA plan if they met one of the following criteria:
  a. Developed ESRD while already enrolled in an MA plan
  b. Received health benefits through the same organization (such as a group health plan) that offers the MA plan.
  c. Had a kidney transplant and no longer require dialysis but are entitled to Medicare.
  d. Have a Medicare special-needs plan offered in their geographic area
  e. Enrolled in an MA plan that is later discontinued (onetime right to join another MA plan)

2. Medicare Fee-for-Service (FFS) Coverage Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries

- Effective January 1, 2021, the costs of organ acquisition for kidney transplants will be covered under Medicare FFS for MA enrollees. This change does not apply to kidney transplants incurred by PACE participants.

3. Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks

- The 21st Century Cures Act requires that the specified amount (i.e. MA benchmark based on FFS costs) must be adjusted to remove costs for organ acquisition for kidney transplants.

Enhancements to the Part C and D Programs

1. Reinsurance Exceptions

- CMS is proposing to amend the allowable MA reinsurance options to include obtaining reinsurance for the cost of providing benefits to an individual enrollee which exceed $10,000 in a contract year.
  a. As a second option, an MA organization can purchase first dollar pro rata insurance, but the price of the coverage cannot exceed the cost of purchasing stop loss insurance at the $10,000 threshold.
  b. CMS is open to comments on the reasonability of this threshold and whether a parent organization of an MA organization should be included or considered a separate entity for these purposes.

2. Out-of-Network Telehealth at Plan Option

- In place from the April 2019 final rule, MA plans offering additional telehealth benefits (ATBs) must do so only using contracted providers. Benefits using a non-contracted provider must be considered a supplemental benefit. CMS clarified that a PPO plan is not required to offer ATBs out-of-network, as is the case for all other plan-covered services. However, a PPO can cover out-of-network ATBs as a supplemental benefit.
- CMS is soliciting comment on whether to revise the requirements such that ATBs can be provided by non-contracted providers, where the non-contracted providers satisfy requirements set forth in the April 2019 final rule.

3. Supplemental Benefits, Including Reductions in Cost Sharing

- CMS is proposing clarifications on the flexibilities of cost sharing reductions for Part C supplement benefits.
  a. CMS is clarifying that
    i. cost-sharing reductions may apply to Parts A and B benefits and services that are not basic benefits and
    ii. that these benefits may only be provided as a mandatory supplemental benefit
  b. Other clarifications include:
    i. MA plans would not be able to offer the use of a debit card (currently allowed for covering cost sharing reductions of covered benefits) for purchase of items or services that are not specified as covered.
    ii. The use of debit cards for a basket of benefits from which an enrollee can choose cannot be rolled over into subsequent years.
    iii. Plans may use a receipt-based reimbursement system or provide the dollar amount on a debit card so that the enrollee may pay the cost sharing at point of service.

4. Referral/Finder's Fees

- The current limits on broker/agent compensation include:
  a. Compensation for initial enrollments may not exceed fair market value (FMV).
  b. Compensation for renewal enrollments may not exceed 50% of FMV.
  c. Limitations on referral or finder's fees.
- CMS is proposing:
  i. to clarify the compensation limitations above are on a per-enrollment basis and include referral fees, and
  ii. to remove rules regarding compensation for referrals of beneficiaries for enrollment (finder's fees)

5. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System

- Overview of Changes for Payment Year 2023
  a. The following measures were removed from the Star Ratings starting in Payment Year 2023 (Calendar Year 2022). These changes were already announced and finalized:
    i. Adult BMI (Part C)
    ii. Appeals Auto forward (Part D)
    iii. Appeals Upheld (Part D)
  b. Guardrails were placed on cutpoint changes for non-CAHPS measures. With this change, cutpoints cannot move by more than a specified amount year over year.
- Proposed Changes for Payment Year 2024
  a. Outlier Removal for non-CAHPS Measures
    i. Prior to calculating the cutpoints, contracts that are considered outliers will be removed from the calculation.
    ii. Because there are typically more "low end" outliers than "high end" outliers, this is expected to increase cutpoints and lower the average Overall Star Rating. CMS estimates that this change will save $808.9M in 2024.
  b. Increase the weight for Patient Experience and Access measures
    i. The weight for Patient Experience and Access measures was increased from 1.5 to 2.0 for the Payment Year 2022 Star Ratings.
    ii. CMS has proposed further increasing the weight of these measures for Payment Year 2024. This change will impact contracts differently depending on their performance on these measures. In total, it is expected to increase the average Overall Star Rating and cost $440.8M, offsetting a portion of the savings from the Outlier Removal change described above.
  c. Measures Removed
    i. Rheumatoid Arthritis Management (Part C) is proposed to be removed from the Overall Star Rating Calculation for Payment Year 2024
  d. New Measures Added
    i. The following measures have been added to the display page and will be included in the Stars Calculation for Payment Year 2024. These measures will both qualify as "Process" measures and will receive a weight of 1.0.
      a) Transitions of Care (Part C)
      b) Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C)

e. Contract Consolidations
    i. CMS clarified that if two contracts are consolidating, and one contract is missing data for a specific measures due to data integrity issues, that contract will receive a zero for their measure value in the weighted average.
    ii. This will start for contracts consolidating in 2021.
f. HOS Measure changes. CMS has proposed making two substantive changes:
    i. Change the adjustment to account for case mix changes. Since the HOS measures mark changes in the population over time, changes in population demographics need to be accounted for.
    ii. Increase the minimum required denominator for these measures from 30 to 100.
g. Statins Use in Persons with Diabetes
    i. This measure is currently an "Intermediate Outcomes" measure, meaning it should receive a weight of 3.0 after the first year.
    ii. CMS is proposing to change this measure to a "Process" measure, so that the measure will continue to have a weight of 1.0 even after the first year.
h. QBP Ratings for New Contracts under existing Parent Organizations
    i. The current rules for determining the QBP rating for new contracts under existing parent organizations were codified, but no changes from prior methodology was made.

6. Permitting a Second "Preferred" Specialty Tier in Part D

- Previously, plans were not permitted to have more than one specialty tier in their formulary. Because of factors such as the introduction of biosimilar biological products to the market and recent higher pricing of some generic drugs relative to brand drug costs, stakeholders requested this policy be reconsidered claiming that an additional specialty tier could improve the ability of Part D sponsors to negotiate with pharmaceutical manufacturers and help lower the prices of high-cost Part D drugs. MedPAC also suggest that the additional tier could be used to encourage the use of lower-cost biosimilars and encourage competition amongst specialty drugs.
- CMS proposes to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts Part D drugs on these tiers from tiering exceptions to non-specialty tiers.
- Both tiers are subject to the specialty drug cost threshold
    a. The cost used to determine whether the drug is eligible to be considered specialty is based on a 30-day equivalent supply ingredient cost reported on the PDE.
    b. This is a change from current policy which uses the negotiated price to determine the threshold as the ingredient cost is more transparent and less complex than the negotiated price.
    c. CMS plans to analyze the specialty cost threshold on an annual basis and update if the current threshold no longer represents the top 1% of 30-day equivalent ingredient costs and would result in a 10% or more change to the threshold.
    For example, if the updated threshold based on the 99th percentile of ingredient costs was calculated to be $685, this only equates to a 2.2% increase compared to the current $670 threshold and would therefore not result in an update.

- Using this updated methodology
  a. CMS has calculated the 2021 contract year specialty tier eligibility threshold to be $780 ingredient cost as opposed to 2020's $670 negotiated price.
  b. If a drug has little or no experience to determine the historical ingredient cost, CMS proposes that plans use the 30 day equivalent negotiated price to determine if the drug is eligible to be placed on the specialty tier.
- Both specialty tiers are subject to a maximum allowable cost sharing between 25% and 33% depending on whether the plan includes a deductible
  a. Further, if the plan has two specialty tiers, one must be a "preferred" tier with lower cost sharing than the non-preferred tier subject to the max allowable cost-sharing. For example, if a plan offers a member coinsurance of 33% on their higher-cost specialty tier, the "preferred", lower-cost specialty tier must have a coinsurance less than 33%.
  b. There is no minimum difference between the two specialty tiers.
- Tiering Exception Proposals include:
  a. Permitting Part D sponsors to design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers.
  b. Requiring Part D sponsors to permit tiering exceptions between their two specialty tiers. That is, Part D sponsors would be required to permit tiering exception requests for drugs on the higher cost-sharing specialty tier to the lower cost-sharing specialty tier.
- Despite comments requesting the lower-cost specialty tier only including generic and biosimilar drugs, CMS' proposal allows Part D sponsors flexibility in which drugs are on the specialty tiers.
- CMS is soliciting comments on a number of the topics discussed above, including comments with regard to:
  a. Permitting Part D sponsors to exempt drugs on either specialty tier from the tiering exceptions process altogether.
  b. Whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.
  c. Actuarial equivalence and the potential for discriminatory effects plan designs with two specialty tiers if we were to permit:
     i. the higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing we have proposed; or
     ii. a maximum allowable cost sharing of 25 percent without regard to deductible
  d. Whether Part D sponsors should restrict the lower cost-sharing, preferred specialty tier to only generic drugs and biosimilar
  e. Specifying that the specialty ingredient cost threshold be round up to the nearest $10 increment instead of rounded down.

7. Beneficiary Real Time Benefit Tool

- Part D plans are required to support a prescriber real-time benefit tool by January 1st, 2021.
  a. The tool must:

    i. Integrate with at least one EHR system
    ii. Provide enrollees with formulary and benefit information, including cost, formulary alternatives, and utilization management requirements (step therapy, quantity limits, prior authorization)
  b. Part D plans are required to support a beneficiary real-time benefit tool accessible by computer or mobile device by January 1st, 2022 (date open to comment).
  c. This information would also be required to be available by call center
  d. It could also be an add-on to existing patient portals
  e. Both RTBT's would have to consider how costs vary depending on the benefit phase the member is currently in.
  f. CMS reminds plans to consider potential compliance issues regarding accessibility for users who are deaf, hard of hearing, blind, or have other impairments
- The information required for the beneficiary and prescriber RTBT's is substantially similar, but differ in the following ways:
  a. Prescriber RTBT's must show all medication alternatives
  b. Part D sponsors would be permitted to have their Pharmacy and Therapeutics committees evaluate whether certain medications should be excluded from the beneficiary RTBT. Excluded drugs should meet one of the following criteria:
    i. Formulary alternatives with significant negative side effects and would not typically be a first choice for prescribing due to the side effects
    ii. Drug of last resort
    iii. Interactions with other prescriptions contra-indicate the drug
    iv. Other clinically appropriate instances
  c. CMS expressly forbids plans from omitting alternatives due to cost implications to the plan or beneficiary
  d. If drugs are excluded from the beneficiary view, plans are required to inform the beneficiary and justify why these alternatives are excluded
  e. The beneficiary RTBT must be devoid of commercial purposes, including:
    i. Presentation of advertising
    ii. Promotion of choices in the interests of the Part D plan rather than the member
    iii. Promotion of medications or refills based on rebates
  f. The beneficiary RTBT should show cost-sharing information that is pharmacy specific based on beneficiary selection (i.e., if the beneficiary indicates that they prefer to go to Walgreens, Walgreens cost info is shown instead of Wal-Mart or an average cost).
  g. Plans are encouraged, but not required, to include the negotiated price
- CMS hopes these changes will improve medication adherence by reducing costs and allowing patients to take a more direct and active role in their health decisions
  a. CMS believes these changes are appropriate as technology becomes a more integral part of seniors' lives:
    i. 40% of seniors now own smartphones
    ii. 82% of 65-69 year olds classify themselves as internet users
- Plans may offer rewards and incentives to members who use the beneficiary RTBT, whether through a portal/application or through the call center.
  a. Rewards may not waive copayments or deductible amounts, or transfer items/services for free
  b. No cash/monetary donations

c. Only gift cards or cash equivalents are allowable, and only those that do not encourage members to spend more money with the plan or its subsidiaries and affiliates
d. Must be of nominal value, defined as no more than $15 per login with an annual max of $75
e. Rewards and incentives may not be contingent on medical diagnoses, prescriptions, or outcomes (i.e., you cannot reward the member for making a brand to generic switch – just for using the tool).

8. Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

- Section 423.514(a) requires each Part D sponsor to have a procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following:
  a. the cost of its operations;
  b. the patterns of utilization of its services;
  c. the availability, accessibility, and acceptability of its services;
  d. information demonstrating it has a fiscally sound operation; and
  e. other matters as required by CMS.
- CMS is considering a new reporting requirement for Part D plan sponsors to disclose the pharmacy performance measures that they use to evaluate pharmacy performance.
  a. The purpose is to predict reimbursements for pharmacies and cost-sharing for beneficiaries
  b. CMS would publish the list of pharmacy performance measures for transparency and to support collaboration and consensus in the pharmacy industry
- CMS is also considering collecting retrospective information on the number of pharmacies by pharmacy type that met and did not meet established thresholds.
- CMS is encouraging the industry to continue to work together to develop a set of pharmacy performance measures that CMS can adopt and standardize
- Goals of reporting requirements should include following criteria:
  a. Improved medication use and outcomes for the beneficiaries served;
  b. Be specified at the right level of attribution and appropriate level of comparison considering pharmacy type;
  c. Factor in both pharmacy accountability and drug plan performance goals;
  d. Have clear specifications and be established prior to the measurement period;
  e. Be reliable, transparent and fair; and
  f. Use threshold minimums if appropriate.

9. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

- Supplemental Benefits
  a. CMS is proposing to revise the regulations at § 422.100 to codify sub regulatory guidance and statutory changes that have expanded the types of supplemental benefits that MA plans may include in their plan benefit packages (PBPs). The proposed amendment to § 422.100(c)(2) would codify CMS's longstanding interpretation of the statute to require a supplemental benefit to be an item or service

i. that is primarily health related, such that the benefit diagnoses, compensates for physical impairments or acts to ameliorate the functional or psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization;
ii. for which the MA organization incurs a non-zero direct medical cost; and
iii. that is not covered by Medicare Parts A, B, or D
iv. to be considered "primarily health related," a supplemental benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one

- Chronically Ill SSBCI
  a. CMS is proposing to codify regulation text implementing amendments made by the BBA of 2018 to section 1852(a)(3) of the Act to expand the types of supplemental benefits that may be offered to chronically ill enrollees, starting in contract year 2020. MA organizations may provide SSBCI that are not primarily health related to chronically ill enrollees, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function.
- Non-Traditional Providers
  a. Current regulation is that incurred claims in the MLR numerator include payments to providers.
  b. A provider is defined as being an individual or entity engaged in the delivery of health care services and who is licensed or certified by the State to engage in that activity in the State.
  c. CMS is proposing to amend it to include all services that meet the "primarily health related standard" covered under the plan benefit package, including those that may not have been furnished by a provider.
- MLR Credibility
  a. CMS proposes to codify in the federal register the definitions of partial, full and non-credibility and the calculations for determining the credibility adjustment which remain unchanged from the May 2013 MLR final rule.
- MLR Credibility for MSAs
  a. CMS is proposing to multiply the base credibility adjustment by a "deductible factor" to recognize the variability of claims for plans with higher deductibles.
  b. The deductible factors would be the same as adopted under the commercial MLR regulations with a caveat that CMS may amend these to be more Medicare specific at a later point.

10. Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests (§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600)

- CMS is proposing regulations for withdrawing or dismissing Part C organization determination and reconsideration requests and Part D coverage determination and redetermination requests. There is some confusion as to when plans can withdraw or dismiss requests. This proposal seeks to codify current practices.

11. Methodology for Increasing Civil Money Penalties (CMPs) (§§ 422.760 and 423.760)

- CMS has the authority to issue CMPs and finalized the CMP calculation in June 2019.
- CMS is proposing the following:
  a. To increase the per determination and per enrollee standard minimum penalty amounts as well as the associated aggravating factors by OMB's cost-of-living multiplier
  b. To update the minimum penalty and aggravating factor at least every three years

Codifying Existing Part C and D Program Policy

1. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services

- CMS is proposing to codify a multi-year transition process for calculating the maximum out-of-pocket limit (MOOP).
- The goals of this codification are to:
  a. Reflect that ESRD beneficiaries will have greater access to MA plans.
  b. Be transparent in the calculations in order to allow MA plans to anticipate future years' MOOP amounts and therefore offer stable benefits over the long term.
- CMS proposes that section 422.101(d)(2) (imposes the MOOP limit for in-network MA regional plans) be revised to cross-reference MOOP limits set for MA local plans at section 422.100(f)(4).21
- Beginning in 2022, CMS is establishing authority for up to three MOOP limits. The three limits would be:
  a. The mandatory MOOP limit (set at 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending).
  b. The intermediate MOOP limit, calculated as the numeric midpoint of the lower and mandatory MOOP limits.
  c. The lower MOOP limit (set at 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending).
- The MOOP limits will be recalculated each year, but will be subject to maximum change percentages and rounding rules in order to stabilize year-to-year fluctuations.
- Incorporation of ESRD beneficiary costs will be phased into the MOOP calculation by taking an increasing percentage of the "ESRD Cost Differential" each year. The ESRD Cost Differential is the difference in Mandatory MOOP limit with both non-ESRD and ESRD beneficiaries included and Mandatory limit with only non-ESRD beneficiary costs. For 2021, CMS proposes to use 60% of the ESRD Cost Differential, with 20% increments thereafter.

2. Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing

- The proposal concerning service category cost sharing limits is intended to:
  a. Codify methods and long standing practices for determining non-discriminatory cost sharing limits
  b. Communicate and codify methods for including ESRD beneficiary experience in determining cost sharing limits to recognize the inclusion of ESRD beneficiaries in MA enrollment in CY 2021.
  c. Propose specific cost sharing limits for inpatient acute and psychiatric stays that are tied to the type of Maximum out-of-pocket (MOOP).
  d. Expand the actuarial equivalency test to all basic benefits covered by an MA plan.

- Specific benefits and limitations are discussed however the proposal includes a catch-all rule intended to provide general guidance and to recognize that not every service category may be discussed.
  a. The proposal codifies the interpretation that payment of less than 50 percent of the MA plan financial liability (enrollee cost sharing plus MA organization payment) discriminates against enrollees who have high health needs.
  b. Regardless of the MOOP, for benefits not otherwise identified with maximum cost sharing requirements, CMS will consider cost sharing that exceeds 50 percent as discriminatory.
  c. For copayments as cost sharing, the copayments for out-of-network benefits may not exceed 50 percent of the average contracted rate or 50 percent if the plan uses coinsurance.
- Effective CY 2021, ESRD beneficiaries will be allowed to choose MA plans for health coverage.
  a. This change in the potential beneficiary pool for MA plans has been reviewed for its impact on cost sharing.
  b. Recent analyses indicate the service category with the largest impact from adding ESRD is inpatient hospital acute length of stay scenarios with the longer length of stay scenarios being the most impacted.
  c. The CY 2021 the Part A deductible ($1,476) does not change with the inclusion of ESRD but the cost sharing limits for longer stays increase as a result of the inclusion of ESRD beneficiary costs.
  d. The rule further codifies the method for including ESRD experience for CY 2022 with 100 percent of ESRD costs included for the development of impatient hospital acute cost sharing limits by CY 2024.
- Benefits that currently have specific cost sharing limitations will continue to have limits on cost sharing.
  a. Added to the list of benefits with cost sharing limits are Home Health and Durable medical equipment.
  b. Other benefits will continue to not have specific cost sharing limitations which is consistent with the higher variation in cost or provider contracting.
  c. As previously discussed that payment of less than 50 percent of the MA plan financial liability is considered discriminatory; although not all benefits have specific cost sharing limitations, the catch-all provision will prevail.
- Effective CY 2022 Cost Sharing limits will be connected with three Maximum-out-of-Pocket (MOOP) limits.
  a. Mandatory MOOP (current Mandatory MOOP): 30 percent coinsurance or actuarial equivalent copay values; MA plan must pay not less than 70 percent of the total MA plan financial liability
  b. Intermediate MOOP (new MOOP level): 40 percent coinsurance or actuarial equivalent copay values; MA plan must pay not less than 60 percent of the total MA plan financial liability
  c. Lower MOOP (current Voluntary MOOP): 50 percent coinsurance or actuarial equivalent copay values; MA plan must pay not less than 50 percent of the total MA plan financial liability
- Historically the actuarial equivalence of cost sharing for inpatient hospital, SNF, DME, and Part B drugs has been a requirement of MA plans. The proposal expands the actuarial equivalence to total cost sharing for all basic benefits covered by the MA plan. The total cost sharing must not exceed cost sharing for those benefits in original Medicare on a Per Member Per Month (PMPM) actuarially equivalent basis.

3. Plan Crosswalks for Medicare Advantage (MA) Plans and Cost Plans

- CMS has proposed to codify the current process and rules for crosswalks of MA plans.
- Crosswalk rules:
  a. MAOs cannot crosswalk from one plan type to another. Different plan types include:
     i. HMO, LPPO, RPPO, and PSO
  b. Enrollees cannot be crosswalked from one SNP type to a different SNP type (e.g. CSNP to DSNP crosswalk)
  c. Crosswalks must occur under plans of the same contract
  d. The enrollees being cross-walked must meet the eligibility requirements of the new plan
  e. If an MA-PD plan is crosswalked into a MA-only plan, the plan sponsor must notify members that they will be losing their Part D coverage and give options for obtaining Part D coverage.
- Types of crosswalks:
  a. Renewal Plan
  b. Consolidated Renewal Plan
     i. Two or more plans combine into one
     ii. The surviving plan must have one of the old PBP numbers
  c. Renewal Plan with Service Area Expansion
  d. Renewal Plan with Service Area Reduction
  e. CSNP specific crosswalks
- Crosswalk Exceptions
  a. the plan must submit a crosswalk exception request in the following situations:
     i. Non-network or partial-network PFFS plans transitioning to partial-network or full-network PFFS plans.
     ii. Contract consolidation – plans moving from one contract to another
     iii. DSNPs crossing multiple states that are requesting a service area reduction to comply with state contracting requirements
     iv. If an organization changes the eligibility criteria for their DSNP and members are no longer eligible for the DSNP, the organization may crosswalk into a DSNP for which the members are eligible
     v. Renewing CSNP crosswalking eligible members to a different CSNP for which they are eligible

4. MA Change of Ownership Limited to the Medicare Book of Business

- CMS states that they will not recognize or allow the transfer or sale of a portion of an organization's Medicare Advantage business. CMS will only recognize the sale if it includes an organization's entire MA business, including all contracts and PBPs in operation.

5. Medicare Advantage (MA) and Cost Plan Network Adequacy

- Currently, CMS requires that organizations contract with a minimum number of providers such that at least 90% of beneficiaries have access to at least one provider or facility of each specialty type with published maximum time and distance standards.

- CMS proposes to codify the existing network adequacy requirements, with some modifications.
- Proposed modifications:
  - ***a.*** Require 1876 cost plans to comply with the network adequacy standards in proposed section 422.116.
  - ***b.*** Exclude MSA plans from requirements in section 422.116.
  - ***c.*** Establish specific provider and specialty types, county types, and time/distance standards by county designation.
  - ***d.*** Annually update and make available the Health Service Delivery (HSD) reference files prior to review of plan networks.
  - ***e.*** Count hospital-based dialysis in network adequacy criteria for the Outpatient Dialysis facility type.
  - ***f.*** Establish CMS authority to remove a specialty or provider types from the network adequacy requirements for a given year.
  - ***g.*** Define the following five county designations:
    1. *Large Metro*
    2. *Metro*
    3. *Micro*
    4. *Rural*
    5. *CEAC (Counties with Extreme Access Considerations).*
  - ***h.*** Set time and distance standards and minimum provider number requirements according to county type. CMS will publish these standards annually in the HSD Reference file.
  - ***i.*** Establish a "customization" process where time and distance standards can be expanded due to a shortage of supply of providers or facilities, or where it is not possible to meet time and distance standards.
  - ***j.*** Reduce the minimum percentage of beneficiaries that must have access to at least one provider/facility of each specialty type within time/distance standards to 85% in Micro, Rural, and CEAC counties (versus 90%).
  - ***k.*** Give MA plans a 10-percentage point credit towards the percentage of beneficiaries residing within time/distance standards for specific provider specialty types if the plan contracts with telehealth providers for those specialty types. Cost plans are not eligible for the 10-percentage point credit. The specialty types are:
    1. Dermatology
    2. Psychiatry
    3. Neurology
    4. Otolaryngology
    5. Cardiology
  - ***l.*** Give MA plans a 10-percentage point credit towards the percentage of beneficiaries residing within time/distance standards for affected provider types in states that have Certificate of Need (CON) laws, or other state anti-competitive provisions that limit the number of providers or facilities in a county or state.
  - ***m.*** Codify "Minimum Ratio" (number of providers required per 1,000 beneficiaries) values by specialty type and county type.

n. Establish a process by which an MA plan can request an exception from network adequacy standards. CMS will evaluate such requests using the following criteria:
    1. Whether current access to providers and facilities is different from the HSD reference and Provider Supply files for the year.
    2. Whether there are other factors present that demonstrate network access is equal to or better than the original Medicare pattern of care.
    3. Whether approval is in the best interest of beneficiaries.

6. Supplemental Benefit Requirements (§§ 422.100 and 422.102)

- CMS is proposing to codify that supplemental benefits must meet the following criteria:
    a. Not covered by original Medicare
    b. Primarily health related
    c. Plan must incur a non-zero direct medical cost
- Primarily Health Related
    a. CMS currently interprets "primarily health related" as meaning the item or service is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization.
    b. CMS is proposing to codify that a supplemental benefit is **not** primarily health related under this definition if it is an item or service that is solely or primarily used for cosmetic, comfort, general use, or social determinant purposes.
    c. CMS notes that supplemental benefits must be medically appropriate to be primarily health related.
    d. In contract year 2020, plans may offer additional supplemental benefits for chronically ill enrollees (SSBCI).
    e. This expansion of supplemental benefits does not affect the expanded scope of the primarily health related supplemental benefit standard discussion above.
- Uniformity Requirements
    a. CMS is proposing to codify the determination that providing access to supplemental benefits that are tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirements in the MA regulations.
    b. CMS proposes to adjust the current rules to specifically state that MA organizations may reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific criteria, provided that similarly situated enrollees are treated the same and that there is some nexus between the health status or disease state and the tailored benefits.

7. Rewards and Incentives Program Regulations for Part C Enrollees (§§ 422.134 and Subpart V)

- Most Rewards and Incentives (R&I) programs fall into the following four areas:
    a. Specified use of plan benefits, for example, rewards provided for obtaining preventive benefits at specified intervals
    b. Following a specific program that promotes exercise and/or good nutrition

c. Participating in specified programs that educate on health matters and/or self-management of nutrition and exercise
d. Specified utilization of plan resources such as hotlines, patient portals, and similar items that facilitate promotion of health

- CMS is proposing to amend the current rule to codify guidance given previously, unify principles governing MA rewards and incentives programs, clarify the requirements of the regulation, and clarify flexibilities available to MA organizations under the regulation.
  a. CMS proposes add to the rule definitions for the following, which can be found in the proposed rule: “Rewards and Incentives program” and several variations of its name; “target activity”; “reward item” and several variations; “qualifying individual”.
  b. CMS proposes a requirement that the qualifying individual must be directly involved and perform the target activity, not the caregiver or other third party individual. Similarly, the reward must be a direct tangible benefit to the enrollee.
  c. CMS is proposing to require that a target activity must be specified, in detail, as to the level of completion needed in order to qualify for the reward item.
  d. CMS proposes adding a new paragraph specifying that a target activity must not be related to Part D benefits.
  e. CMS is proposing to set out anti-discrimination requirements for an R&I program by requiring the program be offered to all qualifying individuals, making accommodations for otherwise qualifying individuals, and be based on enrollee behaviors rather than on desired measurements of health outcomes.
  f. CMS is proposing to set up limitations for rewards, addressing requirements of reward items, addressing prohibitions associated on reward items, and addressing allowances and flexibilities for reward items.
  g. CMS is proposing to codify that violations of R&I regulatory requirements can lead to sanctions.
  h. CMS is proposing to codify current guidance that an R&I program is not a benefit, and the MA organization must include all costs associated with an R&I program as an administrative cost and non-benefit expense in the bid.
  i. CMS is proposing adding a prohibition on mid-year changes to an R&I program.

8. Requirements for Medicare Communications and Marketing (§§ 442.2260 – 422.2274; 423.2260 – 423.2274)

- CMS has adopted regulations related to marketing by MA organizations and Part D sponsors.
  a. These regulations include the specific standards and prohibitions in the statue as well as additional standards and prohibitions promulgated under the statutory authority granted to the agency.
  b. CMS is now proposing to codify the additional guidance contained in the Medicare Communications & Marketing Guidelines (MCMG), a marketing manual intended to provide further interpretation and guidance, by combining the guidelines set forth with the MCMG with the current regulations.

c. The policies that are proposed to be codified are not new to the industry, they are already in place in the MCMG. Please see the proposed rule for full details of these changes.

9. Past Performance (§§ 422.502 and 423.503)

- CMS is proposing a new approach to evaluating past performance of organizations applying for an MA or Part D sponsor contract in relation to previous MA or Part D contracts.
  a. CMS seeks to add clarity and predictability of their review of MA and Part D applicants' prior MA or Part D contract performance by identifying in the regulation text the criteria they will use to make a determination to deny an application based on prior contract performance.
  b. CMS' overall policy with respect to past performance remains the same.
  c. CMS may deny applications based on past contract performance in instances where the level of previous non-compliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees.
- CMS proposes adopting three factors as bases for denying an MA or Part D application:
  i. The imposition of civil money penalties or intermediate sanctions
  ii. Low Star Rating scores
  iii. The failure to maintain a fiscally sound operation
- The presence of any of these factors in an applicant's record during the past performance review period could subject it to the denial of its MA or Part D application.
  a. CMS proposes to exclude intermediate sanctions imposed on dual eligible special needs plans (D-SNPs) during the plan years 2021 through 2025 as a basis for denying a MA or Part D application.
  b. CMS proposes that they will consider the performance of contracts held by the applicant's parent organization or another organization controlled by the same parent and ascribe that performance to the applicant in situations where the applicant has no recent MA or Part D contracting history.

10. Prescription Drug Plan Limits (§ 423.265)

- CMS has made consistent efforts to ensure that the number of PBPs PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choice from among meaningfully different plans.
  a. CMS has declined to approve more than three stand-alone PDPs offered by a Part D sponsor in a PDP region – one basic plan and at most two enhanced plans.
  b. Starting in contract year 2019, CMS eliminated the meaningful difference requirement between enhanced alternative benefit offerings, leading to a greater number of enhanced plan offerings.
  c. Following an analysis of costs with additional enhanced plans, CMS plans to codify the policy of limiting the number of enhanced plan offerings by a Part D sponsor in a PDP region.

d. CMS is seeking stakeholder input as to the impact of limiting the number of enhanced plan offerings to two.
e. CMS is also seeking information on what type of impact expanding the number of enhanced plan alternatives would have and whether there is any real need for more than two standalone enhanced plan options per PDP sponsor per PDP region.

11. Definition of a Parent Organization (§§ 422.2 and 423.4)

- CMS proposed to codify the definition of parent organizations for purposes of the MA and Part D programs as the legal entity exercising controlling interest in an MA organization or Part D sponsor, whether it holds that interest directly or through other subsidiaries.

  a. The proposed rule lists all the reasons that CMS uses the identity of a MA organization's or Part D sponsor's parent organization.
  b. CMS proposes to specify that a parent organization cannot itself be a subsidiary of another entity.

12. Call Center Requirements (§§ 422.111 and 423.128)

- CMS seeks to add greater specificity and clarity to the requirement MA and Part D plans operate a toll-free customer service call center by delineating more explicit performance standards for MA and Part D customer service call centers, as well as ensuring greater protections for beneficiaries.
  a. For the most part, this proposal would codify existing guidance.
  b. CMS proposes to adopt the following performance requirements for call center functionality:
    i. Customer service call centers must be open from at least 8 a.m. to 8 p.m., local time, in all service areas and regions served by the MA or Part D plan.
    ii. For Part D plans, any call center serving network pharmacies or pharmacists employed by those pharmacies must be open any time a pharmacy in the plan service area is open.
    iii. Average hold time must be two minutes or less.
    iv. Call centers must answer 80% of incoming calls within 30 seconds after the Interactive Voice Response, touch-tone system, or recorded greeting interaction.
    v. 5% or less calls can be disconnected or unexpectedly dropped by the plan customer call center.
    vi. Non-English speaking interpreters must be available within 8 minutes of reaching customer service representative and the interpreter must be available at no cost to the caller.
    vii. Call centers must respond to TTY-to-TTY calls, consistent with standards established under existing law governing access for individuals with disabilities.
    viii. When using automated-attendant systems, MA and Part D plans must provide effective real-time communications with individuals using auxiliary aids and services, including TTYs and all forms of FCC-approved telecommunications relay systems.

13. Special Election Periods (SEPs) for Exceptional Conditions

- CMS is proposing to codify a number of SEPs that were previously adopted and implemented through sub regulatory guidance, and to clarify that SEPs are effective as of the first day of the first calendar month following the month in which the election is made.

SEPs for Exceptional Circumstances to Codify	Part C	Part D
Individuals who have (or are enrolling in) an employer or union sponsored plan	X	X
Enrollees in organization that is sanctioned by CMS, if they believe they are affected by the matter(s) that gave rise to that sanction	X	X
Cost plans that are non-renewing their contracts for the area in which the enrollee lives	X	X
Individuals enrolling or disenrolling from PACE	X	X
Individuals who disenroll from an MA plan during a trial period, if a Medigap policy was terminated due to that enrollment, will trigger a Medigap and Part D SEP	X	X
Individuals whose Medicare entitlement determination based on ESRD is made retroactively, and they missed their IECP	X	
Individuals whose Medicare entitlement determination is made retroactively past, and they missed their IECP	X	
Individuals with a qualifying condition to enroll in a C-SNP	X	X
Enrollees in an MA special needs plan (SNP) who are no longer eligible for the SNP	X	X
Individuals in a qualified State Pharmaceutical Assistance Program (SPAP) can enroll in an MA-PD or PDP plan each calendar year	X	X
Individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C-SNP), and individuals who are found not to have the qualifying condition would have a SEP to enroll in a different MA plan	X	X
Individuals who disenroll from an MA-PD or PDP in order to enroll in or maintain other creditable drug coverage (such as TriCare or VA coverage)	X	X
Individuals enrolling in a plan with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating	X	X
Non-U.S. citizens who becomes lawfully present in the United States	X	X

Plan or CMS was unable to provide required notices or information in an accessible format	X	X
If a weather-related emergency or major disaster made an election during another valid election period unavailable	X	X
CMS determines that mid-year changes to a plan's provider network are significant	X	X
Organizations experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the organization in receivership	X	X
Plans identified with the low performing icon (LPI) and enrollee changes election to a plan with an overall Star Rating of 3 or more stars (or to original Medicare)	X	X
Erroneous enrollment or non-enrollment in an MA-PD plan due to an action, inaction or error by a federal employee	X	
Other exceptional conditions established by CMS	X	X

- In addition, CMS is proposing to codify SEPs for Part C and Part D plans to co-ordinate with SEPs for the other. Part C SEPs currently outlined in sub regulatory guidance that coordinate with Part D election periods that are proposed to be codified:
  a. Individuals who have an involuntary loss of creditable prescription drug coverage (not including due to a failure to pay premiums)
  b. Individuals who are not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage
  c. Individuals who are eligible for an additional Part D Initial Enrollment Period (IEP)
- Part D SEPs currently outlined in manual instructions that coordinate with Part C election period that are proposed to be codified:
  a. Individuals who are not entitled to premium free Part A and who enroll in Part B during the GEP
  b. Individuals who disenroll from a cost plan with an optional supplemental Part D benefit
  c. Individuals who meet the definition of "institutionalized" as defined by CMS
  d. Individuals who elect original Medicare during the MA OEP

Proposed Changes to the Programs of All-Inclusive Care for the Elderly (PACE)

1. Service Delivery Request Processes Under PACE

- CMS proposes simplifying how PACE organizations and participants make, handle and respond to Service Delivery Requests in order to strengthen protections for participants and ease the administrative burden on PACE organizations.
- A service delivery request is a request by a participant, caregiver, or designated representative to initiate, modify, or continue a service.
  a. Example: a patient requests increasing their home care hours from 3 to 6 hours per week because they are becoming less steady in their gait and are afraid to be at home alone for long periods of time

b. Service delivery requests must be brought to the interdisciplinary team (IDT) within 3 days of being received, and must be determined within another three days

- The following changes would help reduce administrative burden on PACE organizations:
  a. Requests that can be immediately approved in full by a single member of the IDT would not have to be vetted by the full IDT
  b. Would not have to conduct a full re-assessment of the patient to make a care recommendation unless the request is fully or partially denied
  c. Would not have to provide separate approval notice
  d. Avoids the appeals process

2. Appeals Requirements under PACE

- The appeals process is currently implemented inconsistently, and there is not much participant awareness surrounding it.
  a. CMS proposes allowing a participant's designated representative to appeal on the participant's behalf, and to allow both oral and written appeal requests. Further, PACE organizations must process a service delivery request before processing an appeal
  b. CMS wants to clarify that dual-eligible PACE beneficiaries have the right to appeal through the Medicare or Medicaid processes, and the PACE organization is obligated to help them choose the best appeal option for them

3. Access to Data and Safeguarding Records Under Pace

- CMS and the State must be able to obtain information necessary for their complete audit of the PACE organization
  a. PACE organizations must maintain all written communications received from a participant or other parties when related to the care, health, and safety of a participant

4. PACE Services, Excluded PACE Services, and the Interdisciplinary

- The IDT must consider the participant's medical, physical, emotional, and social needs when making a care determination.
  a. The IDT must also take into account current clinical practice guidelines and professional standards of care if applicable to a particular service
  b. CMS proposes removing language stating that non-authorized services are excluded from coverage, even if they are required services
  c. CMS specifically mentions that this language is being removed because some PACE organizations have denied certain types of covered Part D drugs, even when they are medically necessary

d. The IDT is responsible for caring for their patients, but may not interact directly with them as much as other caregivers. CMS proposes requiring the IDT to take input from other individuals into account when making care determinations, and to document all recommendations for care and services.

5. Documenting and Tracking the Provision of Services under PACE

CMS seeks to clarify existing law to improve the compliance of PACE organizations. Specifically, they want to prevent PACE organizations from taking actions that act against the core tenets of the program, including:

a. Denying or restricting medically necessary services
b. Not providing 24 hour/365 day care and services
c. Relying on caregivers to provide care instead of employees or contractors
d. CMS also wants to make sure that PACE organizations focus more on executing their care plan than creating it, and that they properly document and track all services provided

6. Documentation in Medical Records under PACE

- CMS proposes adding language that compels PACE organizations to document recommendations for care and treatment, decisions regarding those recommendations, and communications relating to a participant's care, health or safety.
  a. For example, if a caregiver emails a recommendation to add extra home care hours for a patient, the PACE organization would have to document this request, their rationale for approving or denying the request, and maintain the original email in the medical record

7. PACE Participant Rights: Contact Information and Access Requirements

- CMS proposes explicitly stating three participant rights to increase awareness of the beneficiary protections afforded to PACE participants:
  a. Right to contact 1-800-MEDICARE
  b. Right to have reasonable access to specialists
  c. Right to necessary care across *all* settings, including LTC if necessary

8. Enforcement Action Appeal Rights under PACE

- CMS proposes to codify existing policy to clarify that PACE organizations have the same rights to appeal enforcement actions as MA organizations.

9. PACE Definitions

- CMS proposes modifying the definition of the services provided by PACE organizations to explicitly include items and drugs to clarify that PACE organizations are responsible for providing Part D drug coverage to participants.

Technical Changes

1. Exclusion of Services Furnished Under a Private Contract

- Proposed changes to wording revolving opt-out providers
  a. If a beneficiary enters into a private contract with a provider this is "opted out"
- CMS believes that supplemental benefits are outside of the scope of restrictions on payments to "opted out" payments

2. Disclosure Requirements

- Proposing to codifying into existence issuance cycles for EOBs
- Currently can choose quarterly or monthly

3. *Effective Date for Exclusion of Coverage for Kidney Acquisition*

- No longer covered 1/1/2021

4. *Effective Date for Exclusion of Coverage for Kidney Acquisitions from Basic Benefits*

- CMS establishes that effective January 1, 2021, MA plans will no longer cover organ acquisitions for kidney transplants.

5. *Add Back Cost Plan Related Sections*

- An entity seeking to offer an MA organization may not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

6. *Definition of "Institutionalized" for ISNPs*

- Intending to incorporate additional types of long-stay facilities to expand access
  a. SNF as defined in section 1819(a) of the Act;
  b. NF as defined in section 1919(a) of the Act;
  c. Intermediate care facility for the mentally retarded (ICF/MR) as defined in section 1905(d) of the Act (now generally referred to as an intermediate care facility for the intellectually and developmentally disabled);
  d. Psychiatric hospital as defined in section 1861(f) of the Act;
  e. Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act;
  f. LTC hospital as defined in section 1886(d)(1)(B) of the Act; or
  g. Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital).
- Acknowledgement that this does not align with rule; the beneficiary has to be dual

7. *Medicare Electronic Compliant Form*

- Making plans to put a link to CMS website for complaints.

8. *Advance Notice and Announcement of Part D Risk Adjustment Factors*

- Codify into law the PD RA Factors are released with advance notice.

9. *Advance Notice and Announcement of Part C Annual Capitation Rate, Benchmarks, and Methodology Changes*

- Codify into regulations the requirement of 60 days advance notice with 30 day comment period (previously regulation said only 15 day comment period).

10. *General Requirements for Applicable Integrated plans*

- Wording changes to esoteric laws.

11. *Representatives in Part D Appeals*

- Identify who is a representative in the appeals process

12. *Copayments and Coinsurance in Amount in Controversy Calculations*

- The appeals law amended to include copayments in it. Original only referred to coinsurance.

13. Beneficiaries with Sickle Cell

- Beneficiaries with disease should be exempted from Drug Management Programs.

14. Drug Management Programs (DMPs): Additional Requirements

- Clarified language and references to the regulations.

Please contact Tim Courtney at timc@wakely.com or your Wakely client manager with any questions or comments. The following Wakely consultants contributed to the development of this summary document: Adam Rudin, Alison Pool, Casey Gardner, Colin Williams, Dani Cronick, Jackie Young, Julia Lambert, Kelsey Stevens, Mary Sullivan, Rachel Stewart, Robert Lang, Thomas Grivakis, and Tim Courtney