National PACE Association
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Memorandum

TO: NPA Members
FROM: Charles Fontenot
DATE: January 12, 2023
RE: Summary of Select Provisions (Part D and Broader Policies) in the Contract Year (CY) 2024 Policy and Technical Changes to the Medicare Advantage, Part D, and PACE Programs Proposed Rule (CMS–4201–P)

On December 27, 2022, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule in the *Federal Register* providing for policy and technical changes to the Medicare Advantage (MA) program, the Medicare Part D prescription drug program, and PACE for CY 2024.

This summary provides an overview of broader provisions in the rule that, while not directly applicable to PACE, may have implications to PACE organizations (POs), in part because they are Part D plan sponsors. The following provisions are those we believe are applicable to PACE. To be assured consideration, comments must be received by CMS, no later than 5 p.m. on February 13, 2023.

- **Strengthening Translation and Accessible Format Requirements for Medicare Advantage, Part D, and D–SNP Enrollee Marketing and Communication Materials (§§ 422.2267 and 423.2267) (page 79697)**

  CMS has learned that enrollees often must make a separate request each time they would like a marketing or communication material in an alternate language or need auxiliary aids or services. It proposes to specify that those materials be provided to enrollees on a standing basis in any non-English language that is the primary language of at least 5 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. This would apply to MA organizations (MAOs), cost plans, and Part D sponsors. This requirement would also be applied to individualized plans of care for special needs plans (SNPs). CMS also proposes to require fully integrated dual eligible (FIDE) SNPs, highly integrated dual eligible (HIDE) SNPs, and applicable integrated plans (AIPs) to translate required materials into any languages required by the Medicare translation standard.

  This proposed rule clarifies existing policy, therefore the impact to MA organizations, cost plans, and Part D plan sponsors depends on whether, and to what extent, they currently have processes in place to note an enrollee's language preference and need for auxiliary aids and services. As described in this section of this proposed rule, CMS believes many plans would not incur significant cost from the proposed requirement because plans currently comply with the proposal.

- **Health Equity in Medicare Advantage (MA) (§§ 422.111 and 422.112) (page 79479)**

  The current requirement for MAOs to provide services in a culturally competent manner for certain populations would be expanded to include people with limited English proficiency or reading skills; of ethnic, cultural, racial, or religious minorities; with disabilities; who identify as lesbian, gay, bisexual, or other diverse sexual orientations; who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; who live in rural areas and other areas with high levels of deprivation; and otherwise adversely affected by persistent poverty or inequality.

CMS also proposes to require organizations to include providers' cultural and linguistic capabilities (e.g., American Sign Language (ASL)) in their provider directories and to identify certain providers waived to treat patients with medications for opioid use disorder (MOUD) in their provider directories. Finally, MAOs would be required to incorporate one or more activities into their overall Quality Improvement (QI) program that reduce disparities in health and health care among their enrollees.

In support of the Administration's goal of advancing equity for all, CMS ensures its regulations address topics that enable disadvantaged populations to fully access the care that the regulations already allow them to receive. Consequently, CMS is proposing several regulatory updates in the MA program related to health equity.

These proposals include requirements intended to ensure equitable access to MA services, ensure MA provider directories reflect providers' cultural and linguistic capabilities and notate MOUD-waivered providers, ensure MA enrollees with low digital health literacy are identified and offered digital health education to assist them in accessing any medically necessary covered telehealth benefits, and ensure MA organizations incorporate one or more activities into their overall QI program that reduce disparities in health and health care among their enrollees.

CMS believes that the proposed changes would address health disparities in the MA program and could be essential to more broadly supporting other equity-focused efforts across CMS policies and programs.

- **Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116) (page 79488)**

  CMS proposes to add the following provider specialty types to its network adequacy reviews and provide the 10 percent telehealth credit for these providers: Clinical Psychology, Licensed Clinical Social Worker, and Prescribers of Medication for Opioid Use Disorder. It would also explicitly include behavioral health services in the general access to services standards, codify wait time standards for primary care and behavioral health services, clarify that emergency services may include some behavioral health services (meaning prior authorization (PA) may not be applied to them), and require MAOs to add behavioral health services to their programs that coordinate covered services with community and social services.

  CMS continues to evaluate and seek ways to enhance our behavioral health policies to address the healthcare needs of those it serves. To support these goals, CMS proposes regulatory changes that focus on ensuring access to behavioral health services for MA enrollees.

- **Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c)) (page 79699)**

  CMS proposes to revise the intent standard for an "identified overpayment" by removing the existing "reasonable diligence" standard and use the "knowing" and "knowingly" standards under the False Claims Act. As modified, an MAO, Part D sponsor, provider or supplier will be treated as having 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.

  Section 1128J(d) of the Act requires a person who has received an overpayment under the Medicare or Medicaid programs to report and return the overpayment as well as to explain, in writing, the reason for the overpayment. An "overpayment" is defined as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. The term person includes providers and suppliers under Medicare Parts A and B as well as MAOs and Part D sponsors under Parts C and D. Overpayments must be reported and returned by the later of 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable. Through rulemaking, the date of

identification was generally established to be when the "person" has determined or should have determined through the exercise of reasonable diligence, that the person received an overpayment.

This reasonable diligence standard was successfully challenged in court because use of that standard under the rulemaking impermissibly created False Claims Act liability for mere negligence. The False Claims Act requires a "knowing" or "knowingly" intent standard. CMS proposes to amend the relevant provisions of its regulations for Parts A, B, C, and D to remove the existing reasonable diligence standard and adopt, by reference, the False Claims Act definition of "knowing" and "knowingly." Under the proposed rule, an MAO or Part D sponsor will be treated as having 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; the same standard would apply to providers and suppliers under Parts A and B.

- **Changes to an Approved Part D Formulary—Immediate Substitutions (§§ 423.4, 423.100, 423.104, 423.120, and 423.128) (page 79536)**

  (Note: PACE organizations are currently waived of the Part D regulations at 423.104(g)(1); 423.120(a); 423.120(c); 423.128. However, unlike the other proposals mentioned here, this proposal would only affect those PACE organizations that have chosen to utilize a formulary as part of their Part D benefit)

  CMS implemented a multi-step process for review and approval of formularies, including formulary and tiered formulary structure, to ensure they are not likely to substantially discourage enrollment by certain Part D eligible individuals. Anticipating that formularies may change due to new developments, it supports small scale, mid-year formulary changes that allow enrollees to quickly benefit from the latest clinical research, new potentially lower-cost options, or possibly better health outcomes.

  CMS proposes to codify its process for reviewing and approving changes to approved formularies, including defining several types of formulary changes, adopting rules for CMS approval of negative formulary changes, revising requirements for implementation of certain formulary changes that may be made immediately, and updating and streamlining notice requirements.

  Consistent with these requirements, CMS proposes to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

  Realizing that implementing new developments may require formulary changes, CMS supports formulary changes that would allow enrollees to quickly benefit from the latest clinical research, new potentially lower-cost options, or possibly result in better health outcomes.

- **Expanding Eligibility for Low-Income Subsidies (LIS) Under Part D of the Medicare Program (§§ 423.773 and 423.780) (page 79478)**

  Beginning January 1, 2024, the Inflation Reduction Act (IRA) expands eligibility for the full low-income subsidies (LIS) to individuals with incomes up to 150 percent of the federal poverty level (FPL) and permits individuals to qualify for the full subsidy based on the higher resource requirements currently applicable to the partial LIS group. CMS proposes to implement this policy.

  Currently, for individuals to be eligible for the full LIS subsidy, they must live in 1 of the 50 states or the District of Columbia (DC) and meet the income and resource standards established in section 1860D-14(a)(3)(D) of the Social Security Act and codified at CFR 42 §423.773. That is, their countable income must be below 135 percent FPL, with countable resources based on three times the SSI resource limit. The 2023 LIS resource limits are

$9,090 for a single beneficiary and $13,630 if married. The partial LIS subsidy is for beneficiaries in the 50 states or DC who are ineligible for full LIS, have income below 150 percent FPL and, for 2023, have countable resources below $15,160 for a single beneficiary and $30,240 if married.

Section 11404 of the IRA expanded the full LIS subsidy group to include those who would qualify under the partial LIS standards, beginning January 1, 2024. CMS proposes regulations to implement the expanded full LIS eligibility and to sunset the partial LIS after 2023. Thus, beginning in 2024, individuals at 135-150 percent FPL who meet the resource requirements would qualify for a premium subsidy of 100 percent of the premium subsidy amount, rather than on the current sliding scale.

If you have questions regarding this information, please contact Charles Fontenot, NPA's Senior Director of Health Plan Management and Reimbursement Policy.