Center for Medicare Advocacy

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**Special Report: Recent Changes in Law, Regulations and Guidance Relating to Medicare Advantage and the Prescription Drug Benefit Program**

**Summary of Changes**

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## Introduction

Numerous changes were made to Medicare law, regulations and guidance during the first half of 2018. The changes are particularly noteworthy regarding Part C, governing private Medicare plans, known as Medicare Advantage (MA), and Part D, the prescription drug benefit. This report focuses on the impact to Medicare beneficiaries from changes to Parts C and D, pursuant to the Bipartisan Budget Act of 2018 (BBA), a final rule issued on Parts C and D (CMS-4182-F), and the Final Call Letter for 2019.[i]

While the BBA made a number of significant changes to Medicare beyond Parts C and D, those changes are not generally discussed here.[ii] Instead, this report highlights many of the changes to MA and Part D most relevant to Medicare beneficiaries and those supporting or assisting them. Part I of the report provides a summary of these changes, along with relevant citations, and is organized by changes to MA, Part D and changes that impact both programs. Part II of the report considers the potential impact of some of these changes, particularly with respect to MA benefits, consumer decision-making and informed choice, and the impact of the changes on the traditional Medicare program.

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**Summary of Changes**

## A. Part C - Medicare Advantage

The **Bipartisan Budget Act of 2018 (BBA 2018)**[iii] makes several changes to Medicare Advantage, including the following:

1. *Expanding Supplemental Benefits to Meet the Needs of Chronically Ill Medicare Advantage Enrollees* – Section 50322 of the BBA states that starting in plan year 2020, MA plans can provide supplemental benefits to chronically ill enrollees. Supplemental benefits are defined as benefits that have "a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits." A "chronically ill enrollee" is defined as someone who "has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of enrollee; has a high risk of hospitalization or other adverse health outcomes; and requires intensive care coordination." (See discussion below comparing this provision with new MA supplemental benefits pursuant to the Final C and D rule.)

2. *MA Special Needs Plans (SNPs) Permanently Reauthorized* – Previously set to expire in 2018, Section 50311 of the BBA permanently reauthorizes Medicare Advantage Special Needs Plans (SNPs). The Act imposes several additional changes for SNPs, including: beginning in 2020, SNPs that target enrollment to individuals with certain chronic or disabling conditions (C-SNPs) are required to meet additional requirements to improve care management for enrollees with severe or disabling chronic conditions. The Act also mandates enhanced coordination between states and federal government surrounding SNPs that serve individuals dually eligible for Medicare and Medicaid (D-SNPs), including unified appeals and grievances procedures and integration of Medicare and Medicaid long-term services and supports and/or behavioral health services, both by 2021.

3. *Expands Value Based Insurance Design* (VBID) *Demonstration* to all states in 2020. As described by CMS, the MA "Value-Based Insurance Design (VBID) Model is an opportunity for Medicare Advantage plans to offer supplemental benefits or reduced cost-sharing to enrollees with Centers for Medicare & Medicaid Services (CMS)-specified chronic conditions, focused on the services that are of highest clinical value to them. The model tests whether this can improve health outcomes and lower expenditures for Medicare Advantage enrollees."[iv] VBID is currently limited by plan, geography and health conditions that are subject to being tested. Section 50321 of the BBA extends the VBID model to all states, as of 2020. (See discussion below comparing VBID to MA uniformity flexibility.)

**Parts C and D Rule and Call Letter**

Changes to MA pursuant to the **Parts C and D Rule** and the **Call Letter** are discussed together in the following section, and most are effective as of the 2019 plan year. (References to updated Medicare Manuals are also included.) The following two changes related to expanding health-related supplemental benefits and new flexibility in uniformity requirements should be reviewed together, for these changes will combine to broaden the scope of items and services available to MA enrollees, while also increasing the difficulties for individuals wishing to make informed choices about their coverage options. **In short, more benefits will be available to**

**certain, but not all, individuals, based on particular health conditions chosen by individual plans.** (See Part II for further analysis.)

1. *MA Uniformity Flexibility* – Previously, the Medicare Advantage uniformity standard outlined at 42 CFR §422.100(d) was interpreted to mean that plan sponsors had to offer all enrollees in a plan in a given service area access to the same benefits at the same level of cost-sharing. CMS is reinterpreting this uniformity requirement[v] to allow plans to "reduce cost-sharing for certain covered benefits, offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the medical criteria identified by the MA plan for the benefits) are treated the same. In addition, there must be a nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state."[vi] **In other words, MA plans can offer targeted benefits and/or reduced cost-sharing, at their discretion, based upon enrollees' particular health condition(s).** Targeted supplemental benefits include the new, expanded interpretation of supplemental benefits discussed below.

    a. Plan sponsors may determine which diagnoses or health conditions they choose to target for these new benefits, and will be responsible for developing the criteria to identify enrollees who fall within each of the clinical categories selected by the plan. In identifying eligible enrollees, plan sponsors must use medical criteria that are objective and measureable, and the enrollee must be diagnosed by a plan provider or have their existing diagnosis certified or affirmed by a plan provider. Such objective criteria should be contained in written policies "that are clearly and adequately communicated to enrollees" such as in the Evidence of Coverage and other plan documents.[vii]

    b. This reinterpretation applies to "MA benefits only" (meaning items and services covered under Parts A and B of Medicare) and does not permit changes to Part D cost-sharing or Part D benefits. This flexibility also does not apply to premiums; beneficiaries in the same plan must have the same premium.[viii]

    c. Plans can reduce cost-sharing for subsets of "high quality providers" and MA plans can identify high-value providers across all Medicare provider types - including physicians, hospitals, skilled nursing facilities, home health agencies, etc.[ix]

    d. MA plans are required to include flexibility information in their Evidence of Coverage (EOC) documents for 2019, and "indication of additional benefits and/or reduced cost-sharing for enrollees with certain health conditions will be displayed in Medicare Plan Finder."[x]

    e. On April 27, 2018, CMS issued additional guidance in the form of a memorandum entitled "Reinterpretation of the Uniformity Requirement" which will be incorporated into Chapter 4 of the Medicare Managed Care Manual. The memo included the following clarifications:

        i. Plans have the option to limit targeted benefits to enrollees who agree to participate in a plan sponsored wellness, care management, or similar program as long as they have equal access (opportunity to enroll/participate regardless of health status, location or disability); cost-sharing reductions or access to targeted supplemental benefits can be conditioned on enrollees meeting certain milestones based on participation (but can't condition them based upon achieving any specific clinical goals);

ii. Plans can choose to offer targeted benefits to enrollees when they visit providers identified by the plan as being "high-value" providers, who must be "available and accessible to applicable targeted enrollees";
iii. PPO plans offering additional supplemental benefits must offer the benefits both in and out of network, though higher cost-sharing for out-of-network benefits is permitted; however, PPOs are not required to extend the reduction in cost-sharing to out-of-network benefits.;
iv. Coverage requests from enrollees and providers related to targeted benefits should not be treated differently from requests for other benefits furnished by the MA plan. Thus, if a request fits under the definition of an organization determination per 42 CFR §422.566(b), such determination is subject to appeal;
v. Targeted benefits must be medically related to each health status or disease state; social determinants may not be used as a means to target benefits, even those benefits related to health (e.g., homelessness, food insecurity);
vi. MA organizations may process reduced cost-sharing for targeted enrollees through retroactive reimbursement; plans may not use different cost-sharing amounts that are based on the cumulative amount of visits, however plans are permitted to limit the maximum aggregate dollar amount of reduced cost-sharing.

2. *Expanding Health-Related Supplemental Benefits* - Under current MA rules, a plan sponsor can offer supplemental benefits defined as "an item or service not covered by original Medicare, that is primarily health related and for which the MA plan must incur a non-zero direct medical cost."[xi] Such "item or service must be primarily health related; that is, the primary purpose of the item or service is to prevent, cure or diminish an illness or injury. If the primary purpose of the item or service is comfort, cosmetic or daily maintenance, then it is not eligible as a supplemental benefit." Supplemental benefits must be offered to all enrollees in the plan, and typically include things such as vision, hearing and dental services.

a. In the Final 2019 Call Letter, CMS states that it is "expanding the scope of the primarily health related supplemental benefit standard." Whether a service or item is "primarily health related" will be determined under a three-part test for supplemental health care benefits: It must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization.[xii]
b. CMS adds: "Supplemental benefits under this broader interpretation must be medically appropriate and recommended by a licensed provider as part of a care plan if not directly provided by one; supplemental benefits do not include items or services solely to induce enrollment."[xiii]
c. BBA Supplemental Benefits v. Supplemental Benefits Available Via the 2019 Regulatory Changes – As discussed above, the BBA provides for a new type of supplemental benefit starting in 2020; according to CMS, these BBA benefits are qualitatively different than those that will be available in 2019 via the regulatory change because they are only for those who are chronically ill, and can be provided only if there is a reasonable expectation of improving or maintaining health/function (can be tailored to individual enrollee's specific conditions and

needs, rather than a group of similarly situated enrollees with the same health condition(s)). In addition, the BBA benefits will not be limited to the primarily health related standard, so it will be possible "to address issues beyond a specific medical condition, such as social supports" but the basis for offering such benefits will be based solely on an enrollees' qualification as "chronically ill" and "may not be based on conditions unrelated to medical conditions, such as living situation and income."[xiv]

d. Three Types of Supplemental Benefits – In the preamble to the final rule, CMS explains the different forms of supplemental benefits, which plans will have to explain in Evidence of Coverage (EOC) documents:[xv]

   i. "Standard" – Offered to all enrollees (available now, as discussed above);

   ii. "Targeted" – Offered to qualifying enrollees by health status or disease state (starting in the 2019 plan year, as discussed in this section); and

   iii. "Chronic" – Offered to chronically ill, pursuant to the BBA (starting in 2020); not limited to being primarily health related; possible to go beyond a specific medical condition, such as social supports.

e. On April 27, 2018, CMS issued additional guidance in the form of a memorandum entitled "Reinterpretation of 'Primarily Health Related' for Supplemental Benefits" which will be incorporated into Chapter 4 of the Medicare Managed Care Manual. The memo includes the following clarifications:

   i. A supplemental benefit is not primarily health related if it is an item or service that is solely or primarily used for cosmetic, comfort, general use, or social determinant purposes;
   ii. Coverage requests from enrollees and providers related to supplemental benefits should not be treated differently from request for other benefits furnished by the MA plan. Thus, if a request fits under the definition of an organization determination under 42 CFR §422.566(b), such determination is subject to appeal;
   iii. Plans must identify what will and will not be covered in the plan's EOC, including any limitations on coverage;
   iv. CMS provides a non-exhaustive list of allowable supplemental benefits under this reinterpretation, including: adult day care services, home-based palliative care, in-home support services, support for caregivers of enrollees, medically-approved non-opioid pain management, stand-alone memory fitness benefit, home and bathroom safety devices and modifications, transportation (to obtain non-emergent, covered Part A, Part B, Part D, and supplemental benefit items and services to accommodate the enrollee's health care needs), and over-the-counter benefits.

3. *"Meaningful Difference" Requirement Eliminated* – previously, MA plan sponsors offering more than one plan in a given service area had to ensure the plan benefit packages were substantially different from one another with respect to key plan characteristics such premiums, cost-sharing or benefits. The rationale for this rule, as noted by CMS in the draft 2019 Call Letter, was "so that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs."[xvi] Despite this rationale, CMS is eliminating this requirement by amending 42 CFR §§422.254 and .256, in part, because it "is concerned the current

requirement may result in organizations reducing the value of certain benefit offerings in order to make their benefit packages comply with these unnecessary limits."[xvii]

4. *Default Enrollment* – The Medicare statute, at 42 U.S.C. §1395w–21(c)(3)(A)(ii),[xviii] currently allows individuals enrolled in a non-MA health plan offered by a health insurance company that also offers an MA plan to be deemed to have enrolled in an MA plan offered by the same company when the person becomes eligible for Medicare, following permission sought by the plans and approved by CMS, and with an opportunity for the individual to "opt-out" of such enrollment. Advocates found that this "seamless conversion enrollment" process led to some individuals being enrolled in MA plans without their knowledge or consent.[xix] Based in part on concerns raised by advocates, CMS imposed a moratorium on approvals of new plan requests in October 2016 pending issuance of new guidance. In the final C and D rule, CMS narrows the scope of seamless conversion enrollments, which require beneficiaries to opt-out of such enrollments, but signals its intent to make it easier for individuals to opt-in to MA coverage from other health coverage offered by the same plan sponsor.
    a. *Seamless Conversion Enrollments* – (Opt-out) into MA Special Needs Plans for dual eligibles (D-SNPs) only, with several conditions, including state and CMS approval, and from affiliated Medicaid managed care plans.
        i. Note: CMS will also allow passive enrollment for full-benefit dually eligible beneficiaries from a non-renewing integrated D-SNP to another comparable plan, after certain conditions are met, including consultation with state Medicaid agency.
        ii. Default Enrollment - CMS is codifying changes to a current enrollment mechanism that allows MA organizations to provide seamless continuation of coverage for their beneficiaries once they become Medicare eligible.
        iii. Passive Enrollment Opportunities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries - In an effort to promote integrated care, continuity of care, and partnership with states, CMS is codifying a limited expansion of its regulatory authority in circumstances when beneficiary enrollment is disrupted by changes in health plan participation. This change allows passive enrollment for full-benefit dually eligible beneficiaries from a non-renewing integrated D-SNP to another comparable plan. This process will be conducted after consulting with a state Medicaid agency, where other conditions are met, to ensure continuity and quality of care.[xx]
    b. *Seamless Continuation of Coverage* – (Opt-in) – This change provides a simplified election process for non-Medicare members (commercial, Medicaid, other) into MA offered by same plan sponsor. While the final rule does not provide much detail, the updated Medicare Managed Care Manual, Chapter 2, provides relevant information:
        i. Sec. 20.4: "Individuals switching plans in the same MA organization may use a shortened enrollment form […]. Individuals new to Medicare who are already a member of the organization's non-Medicare coverage (commercial, Medicaid, ACA Marketplace) may use the simplified enrollment mechanism, if the MA organization chooses to offer it."
        ii. Sec. 40.1.2: "Electronic ICEP enrollment requests from individuals enrolled in a non-Medicare plan under the same organization (or parent organization) and transitioning to

the MA plan without a break in coverage may be based on the simplified opt-in enrollment mechanism as described in §40.1.9."

iii. Sec. 40.1.3: CMS has loosened enrollment restrictions for outbound calls by MA plans: "MAOs may also accept enrollment requests during communications initiated by the organization when, during the course of outreach to provide information about their Medicare plan offerings to individuals with whom they have an existing business relationship, the individual expresses a desire to enroll in one of the organization's MA plans."

iv. Sec 40.1.9 provides more details regarding the simplified enrollment mechanism:

1. "This mechanism permits an MA organization to use data it has from its non-Medicare lines of business (commercial, Marketplace, Medicaid, etc.) to obtain some of the information it would normally need to receive from the beneficiary in the enrollment request. The organization is required to obtain any data necessary from the individual that it doesn't have from its data sharing.

2. Use of this mechanism is not required. It is up to the MA organization whether it has the capability and wants to share data between its Medicare and non-Medicare lines of business.

3. MA organizations may only offer simplified enrollment to individuals who:

   a. Are in their ICEP based on their initial enrollment in Medicare;

   b. Are enrolled in any type of non-Medicare plan under the same organization (or an entity under the same parent organization as the MA organization); and

   c. Do not have a break in coverage between the non-Medicare plan and the MA plan.

5. *Maximum Out-of-Pocket (MOOP) and A and B Cost-Sharing Limits* (42 CFR §422.100(f)(4), 422.101(d) – Starting in 2020, CMS will have authority to change and implement additional levels of MOOP limits, and allow plans greater flexibility in setting cost-sharing limits for Part A and B services in an effort to encourage plan offerings with lower MOOP limits (the voluntary MOOP limit, which allows plans greater flexibility in establishing cost-sharing for Part A and B services, is currently $3,400 and the mandatory limit is $6,700).

6. *MA OEP - Restoration of the Medicare Advantage Open Enrollment Period* (42 CFR §§ 422.60, 422.62, 422.68, 423.38 and 423.40) – CMS proposed regulatory changes to implement the "new" Open Enrollment Period (OEP) required by the 21st Century Cures Act, which replaces the Medicare Advantage Disenrollment Period (MADP) required by the Affordable Care Act (ACA). **Effective 2019, for the first 3 months of the calendar year, there will be a continuous open enrollment and disenrollment period for those individuals enrolled in an MA plan.**

   Unlike the "old OEP" which was in effect prior to the ACA, the "new OEP" permits changes to Part D coverage for those who, prior to the change in election during the new OEP, were enrolled in an MA plan. Therefore, during this 3-month period an MA eligible beneficiary can make a one-time change as

follows: An individual enrolled in an MA-PD plan may use the new OEP to switch to: (1) another MA-PD plan; (2) an MA-only plan; or (3) Original Medicare with or without a PDP. The new OEP would also allow an individual enrolled in an MA-only plan to switch to: (1) another MA-only plan; (2) an MA-PD plan; or (3) Original Medicare with or without a PDP. Further, unsolicited marketing is prohibited by statute during this period.[xxi]

a. See Medicare Managed Care Manual, Ch. 2 §30.5; Also note that §30.6 states that MA plans do not have to accept applications during this time – they can choose to be "open" or "closed" for enrollment during this period .
b. Also see 2019 Communications and Marketing Guidelines §40.7:
    i. During the OEP, Plans/Part D Sponsors may not:
        1. Send unsolicited materials advertising the ability/opportunity to make an additional enrollment change or referencing the OEP;
        2. Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP);
        3. Engage in or promote agent/broker activities that intend to target the OEP as an opportunity to make further sales;
        4. Call or otherwise contact former enrollees who have selected a new plan during the AEP.

7. ***Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE*** - (42 CFR §422.590) CMS proposed eliminating the requirement that MA plans notify an enrollee when a reconsideration decision is deemed adverse or partially adverse to the enrollee and has been referred to the independent review entity (IRE). The rationale for this is that the plan notice is duplicative and nonessential because the Part C IRE is contractually responsible for notifying an enrollee that the IRE has received and will review the case.[xxii]

   In the final regulations, CMS decided to remove the current requirement that MA plans send a notice to an appellant when their appeal case file is forwarded to the IRE. Plans can, however, choose to continue to notify enrollees upon forwarding cases to the IRE. CMS indicated they received strong support for their proposal to eliminate the MA notice when plans forward cases to the Part C IRE. CMS feels that providing this notice is a burden for MA plans and believes the change will increase beneficiary understanding and will allow plans to redirect their resources to more patient-care related, time-sensitive activities.[xxiii]

## B. Part D

**BBA 2018 makes several changes to the Part D prescription drug program, including the following:**

1. *Closes Part D Donut Hole One Year Early* – The Part D coverage gap, or "Donut Hole," will be closed in 2019 for brand name drugs rather than 2020, as mandated by the Affordable Care Act. In 2019, Part D enrollees will be responsible for paying 25% cost-sharing on brand name drugs in the Donut Hole rather than 30% (they will still pay 37% for generics in 2019). Beneficiaries will also enter the catastrophic coverage phase earlier in 2019 since more drug costs will count towards meeting the coverage threshold. BBA §53116.

**The Final Parts C and D Rule significant changes include the following:**

1. *Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) - Drug Utilization Controls (Opioids)* – The Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. Law No: 114-198) requires CMS to establish through regulation a framework that allows Part D sponsors to implement drug utilization control, or management programs. Under such programs, a sponsor can limit "at-risk beneficiaries'" access to coverage for frequently abused drugs beginning with the 2019 plan year (for definitions of "at-risk" and potentially at-risk" see 42 CFR §423.100).

   CMS will designate opioids and benzodiazepines as frequently abused drugs, however clinical guidelines will only consider a beneficiary's opioid use.[xxiv] The clinical guidelines used to determine if a beneficiary is potentially at-risk are based, in part, on using opioids from multiple prescribers and/or multiple pharmacies. Requirements for drug management programs can be found at 42 CFR §423.153(f).

   a. Plan sponsors will be allowed to limit an at-risk beneficiary's access to frequently abused drugs to a selected prescriber(s) and/or pharmacy(ies) ("lock-in"), and through the use of beneficiary-specific point-of-sale (POS) claim edits, which are already permitted under current rules. Part D sponsors may not implement such limitations unless they have engaged in case management with the prescribers of these drugs, and followed proper notice requirements.
      i. Notice from plan sponsor
         1. Initial Notice – After engaging in case management, plan sponsors must provide an initial notice to a potential at-risk beneficiary indicating the sponsor's intent to limit the beneficiary's access to frequently abused drugs. This includes a request that the beneficiary submit to the plan sponsor within 30 days any information relevant to the sponsor's determination, (including which prescribers and pharmacies the beneficiary would prefer the sponsor to select), and an explanation of the right to appeal if the sponsor issues a determination that beneficiary is at risk. If the plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 60 days from the date on the initial notice, the "potentially at-risk" designation will expire. At-risk determinations will be for an initial 12 month period, with plan option to extend for an additional 12 month period.[xxv]
         2. Second Notice – Upon making a determination that a beneficiary is at-risk, the plan must notify him/her of such identification with an explanation of corresponding limitations, including the prescriber(s) or pharmacy(ies) from which frequently abused drugs must be obtained, and an explanation of both standard and expedited redetermination (appeal) process. An appeal right will be triggered by the second notice, not the first notice.[xxvi] If the sponsor decides not to limit access to coverage for frequently abused drugs, the plan will send an alternative notice.
   b. CMS will exempt beneficiaries from drug management programs who: 1) Have elected to receive hospice care or is receiving palliative or end-of-life care; 2) Are residents of a long-term care facility, or of a facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or 3) Are being treated for active cancer-related pain. (See 42 CFR §423.100)
   c. CMS is limiting the availability of the special enrollment period (SEP) for dually or other low income subsidy (LIS) eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such drug management programs. 42 CFR §423.38(c)(4)(ii). If an individual has been notified that s/he has been identified as a "potential at-risk" beneficiary or "at-

risk beneficiary" and such identification has not been terminated, such individual is not eligible for a duals/LIS SEP (as noted elsewhere, SEPs for duals/LIS individuals is being limited to one time per calendar quarter for the first 9 months of the calendar year).[xxvii]

d. At-risk determinations, which include the selection of prescriber and/or pharmacy lock-in, will be subject to the existing beneficiary appeals process. 42 CFR §423.560. This includes expedited appeals.[xxviii]

2. *Part D Tiering Exceptions* (42 CFR §§423.560, .578) – CMS is eliminating the provision allowing plans to exclude a dedicated generic tier from the tiering exceptions process, and establishing a framework based on the type of drug (brand, generic, biological product) requested and the cost-sharing of applicable alternative drugs; cost-sharing for approved requests is at the lowest applicable tier when alternatives are on multiple lower tiers, and authorized generic drugs are treated as generics for purposes of tiering exceptions.

3. *Limitation to the Part D Special Enrollment Period for Dual and Other LIS-Eligible Beneficiaries* (42 CFR §423.38(c)) – Special Election Period (SEP) for dual-eligible and LIS beneficiaries is revised from an open-ended monthly SEP to one that can be used only once per calendar quarter during the first nine months of the year (January through September). Separate SEPs can be used in the following circumstances: (1) Within a certain period of time after a CMS or state-initiated enrollment; and (2) Within a certain period of time after a change to an individual's LIS or Medicaid status. Also see Medicare Managed Care Manual, Ch. 2, §30.4.4.5.

4. ***Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations*** (42 CFR §§423.590 and 423.636) – CMS finalized regulations that will lengthen existing timeframes for adjudicating enrollee Part D payment appeal requests at the redetermination and independent review entity (IRE) reconsideration levels from a maximum of 7 calendar days to a maximum of 14 calendar days. The change will ultimately add another 14 days to denials that are appealed to the IRE where the beneficiary has already obtained the requested medication.[xxix]

5. *Changes to the Days' Supply Required by the Part D Transition Process* (42 CFR §423.120) – Purportedly to reduce waste, CMS is conforming the transition supply provided in the long term care setting (currently 90 days) to the transition supply provided in the outpatient setting (currently 30 days) so that the transition supply in both settings is for the same period. CMS is also changing the "30-day transition supply" to "an approved month's supply" so that it will now be equivalent to the approved month's supply for the applicable plan bid. Thus, Part D sponsors will be required to provide an approved month's supply in both the long term care and outpatient settings.

6. *Expedited Substitutions of Certain Generics & Other Midyear Formulary Changes* (42 CFR §423.120) – The final rule provides more formulary flexibility by, for instance, permitting Part D sponsors to immediately substitute generics for brand name drugs on the same or lower cost-sharing tier if they meet certain requirements, which include generally advising enrollees beforehand that such changes can occur without a specific advance notice and later providing information to affected enrollees about any specific generic substitutions that occur.

7. *Similar Treatment of Biosimilar and Interchangeable Biological Products and Generic Drugs for Purposes of Low Income Subsidy (LIS) Cost-sharing* (42 CFR §422.782) – This provision further encourages the use

of lower-cost alternatives by applying generic cost-sharing to biosimilar and interchangeable biological products for LIS Part D enrollees throughout all phases of the benefit.

8. *Part D Meaningful Differences Between Enhanced Alternative (EA) Plans* (42 CFR §423.265) – CMS is eliminating the "meaningful difference" requirement for PDP Enhanced Alternative (EA) benefit designs offered by the same organization in the same region. CMS is not changing this requirement as it applies between PDP Basic and EA prescription drug plan offerings.

## C. Parts C and D

**The following is a discussion of BBA and regulatory changes that will have an impact on both the Medicare Advantage and the Prescription Drug Benefit Program.**

1. *Further Means Testing Medicare Premiums* – Medicare beneficiaries with incomes of $85,000 (or $170,000 for a couple) already have to pay higher premiums for both Part B and Part D coverage. Pursuant to the BBA, beginning in 2019, individuals with income of $500,000 or more ($750,000 for couples) will pay an even higher share of their premiums than they pay under current law (85% v. 80%). Note that in order to enroll in a Medicare Advantage plan, an individual must have both Parts A and B.

2. *Changes to the Definition of Marketing* (42 CFR §§422.2260, 423.2260) – Previously, a variety of materials that were not intended to steer a beneficiary into a particular plan fell under the regulatory definition of marketing and its related requirements, including a statutory requirement that these materials be subject to CMS review. CMS has changed the definition to include only materials that are most likely to lead a beneficiary to make an enrollment decision. According to CMS, this change "lessens the burden of marketing submission on plans and CMS reviewers. To account for those materials that will now fall outside of the new marketing definition, CMS is adopting more appropriate requirements and oversight for a new category of materials and activities called 'communications.'"[xxx]
    a. See the 2019 Communications and Marketing Guidelines - Section 20.1 states: "communication activities and materials are distinguished from marketing activities and materials based on both intent and content"
        i. Communications means activities and use of materials to provide information to current and prospective enrollees. This means that all activities and materials aimed at prospective and current enrollees, including their caregivers and other decision makers associated with a prospective or current enrollee, are "communications" within the scope of the regulations at 42 CFR Parts 422, 423 and 417.
        ii. Marketing is a subset of communications and includes activities and use of materials that are conducted by the Plan/Part D sponsor with the intent to draw a beneficiary's attention to a MA plan or plans and to influence a beneficiary's decision-making process when selecting a MA plan for enrollment or deciding to stay enrolled in a plan (that is, retention-based marketing). Additionally, marketing contains information about the plan's benefit structure, cost-sharing, and measuring or ranking standards.

However, CMS excludes materials that might meet the definition of marketing based on content, but do not meet the intent requirements of marketing. Additionally, CMS excludes certain required materials (as outlined under section 100), and reserves the ability to exclude additional materials based on their use or purpose.

3. *Allowing Electronic Delivery of Certain Beneficiary Documents* – CMS is separating the delivery date of the Annual Notice of Change (ANOC) from the Evidence of Coverage (EOC) so Medicare beneficiaries receive the ANOC first as a stand-alone document. This is a change that many advocates have endorsed for several years because it will allow beneficiaries to better focus on the most important information, such as the upcoming changes to their current plan. The ANOC must be delivered 15 days before first day of ACEP (10/1), whereas the EOC must by delivered by first day of ACEP (10/15). CMS also will allow MA and Part D sponsors to provide certain materials, such as the EOC, electronically, with hard copies available upon request.
    a. See 2019 Communications and Marketing Guidelines, (Section 100.2, et seq). In particular, see Section 100.2.1, providing that, without prior beneficiary authorization, Plans/Part D sponsors may send existing (i.e., not new) enrollees a notice informing enrollees how to access CMS designated required materials electronically instead of mailing hard copies of the documents. The following required materials may use this process:
        i. EOC [Evidence of Coverage];
        ii. Provider/Pharmacy Directories, and/or;
        iii. Formularies.

4. *Preclusion list requirements for prescribers and providers* – The final rule rescinds the regulatory requirement that prescribers of Part D drugs and providers of MA services and items must enroll in Medicare in order for the drug, service, or item to be covered. Instead, a Part D plan sponsor will be required to reject, or require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on a new "preclusion list." Similarly, an MA service or item will not be covered if the provider that furnished the service or item is on the preclusion list.
    a. The preclusion list will consist of certain individual providers and entities that are currently revoked from the Medicare program under 42 CFR §424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program.[xxxi]

5. *Medical Loss Ratio (MLR)* – CMS finalized the proposal to significantly reduce the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis. Under these new rules, MA organizations and Part D sponsors will only report the MLR percentage and amount of any remittance owed to CMS for each contract. CMS also finalized proposals to revise the MLR calculation to include in the MLR numerator all expenditures related to fraud reduction activities (including fraud prevention, fraud detection, and fraud recovery) and Medication Therapy Management (MTM) programs, not just expenses related to coverage.

6. *New Special Enrollment Periods (SEPs)* – Note that the 2019 Medicare Managed Care Manual, Chapter 2, includes new Special Enrollment Periods (SEPs) at §§30.4.4.17 and .18:

    a. 17. SEP for Providing Individuals who Requested Materials in Accessible Formats Equal Time to Make Enrollment Decisions – Section 504 of the Rehabilitation Act of 1973 (Rev. 1, Issued: July 31, 2018; Effective/Implementation: 01-01-2019); and
    b. 18. SEP for Individuals Affected by a FEMA-Declared Weather Related Emergency or Major Disaster 42 CFR §422.62(b)(4) (Rev. 1, Issued: July 31, 2018; Effective/Implementation: 07-30-2018).

**ENDNOTES**

[i] The Bipartisan Budget Act of 2018 (BBA) was signed into law on February 9, 2018 (Public Law No. 115-123) see Division E – Health & Human Services Extenders; the bill is available here. The final rule for Parts C & D (CMS-4182-F) was published on April 16, 2018 – entitled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program", 83 Fed Reg 16440 (April 16, 2018), is available here (also see this Centers for Medicare & Medicaid Services (CMS) press release summarizing the rule here). The Final Call Letter, which is sub-regulatory guidance, was released on April 2, 2018, formally known as the Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, is available here; also see CMS press releases discussing the Call Letter here and here. Note that some of the descriptions of changes in law and rules are taken directly from summaries provided by CMS.

[ii] For an overview of the Center's analysis of the BBA of 2018, see "Center for Medicare Advocacy Statement on the Health Extenders in the Budget Agreement", February 9, 2018, at: http://www.medicareadvocacy.org/statement-on-the-health-extenders-in-the-budget-agreement/.

[iii] For a section-by-section summary of the Health and Human Services Provisions of the BBA of 2018, see, e.g., https://strategichealthcare.net/wp-content/uploads/2018/02/Bipartisan-Budget-Act-of-2018-HC-Provisions.pdf.

[iv] See the CMS Centers for Medicare and Medicaid Innovations (CMMI) website at: https://innovation.cms.gov/initiatives/vbid/.

[v] CMS states that "[t]his flexibility is not a change to the regulation; it is a reinterpretation of an existing regulation." 83 Fed Reg 16484.

[vi] 83 Fed Reg 16480.

[vii] 83 Fed Reg 16481-3.

[viii] 83 Fed Reg 16482.

[ix] 83 Fed Reg 16483-4.

[x]83 Fed Reg 16484.

[xi] See Medicare Managed Care Manual (CMS Pub. 100-16), Chapter 4, section 30, et seq. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.

[xii] Final 2019 Call Letter, p. 208.

[xiii] Final 2019 Call Letter, p. 208.

[xiv] 83 Fed Reg 16481-3, emphasis added.

[xv] 83 Fed Reg 16482.

[xvi] Draft 2019 Call Letter, p. 170, available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf.

[xvii] CMS April 2, 2018 Press Release, available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02.html.

[xviii] Also see 42 C.F.R. §422.66(d), and Medicare Managed Care Manual, Chapter 2: Medicare Advantage Enrollment and Disenrollment, 40.1.4.

[xix] See the Center for Medicare Advocacy's Weekly Alert, "Case Study: Enrolled in a Medicare Advantage Plan Without Her Knowledge Through Seamless Conversion Enrollment" (June 1, 2016), available at: http://www.medicareadvocacy.org/case-study-enrolled-in-a-medicare-advantage-plan-without-her-knowledge-through-seamless-conversion-enrollment/; also see Joint Advocates letter to CMS (September 30, 2016), available at: http://www.medicareadvocacy.org/wp-content/uploads/2016/10/CMS-Letter-Seamless-Conversion-093016.pdf.

[xx] For more information, see Medicare Managed Care Manual, Ch. 2, §§20.4.2, 30.4.7, 40.1.4.

[xxi] The Center for Medicare Advocacy submitted comments raising concerns that this statutory change favors MA plans and further promotes steering toward MA plans since only those who are enrolled in an MA plan have the advantage of being able to change or pick up a Part D plan. There are no protections for individuals enrolled in traditional Medicare who may want to change their Part D plan or pick up Part D in the first place. The Center also asked that all CMS material and resources, including publications, websites,

and those answering the 1-800 Medicare helpline make it very clear to beneficiaries that they should enroll in a PDP as close to disenrollment from the MA plan as possible to avoid going without prescription drug coverage for a period of time. CMS responded to a number of comments before finalizing the revisions to the corresponding regulations that "restore" the OEP. In response to a comment suggesting that CMS exercise discretionary authority and expand the MA OEP to all beneficiaries, CMS responded that they do not have this discretionary authority of expanding the scope to all beneficiaries and broadening the scope of the election period would contradict the intent of the statute. CMS also indicated that they felt that beneficiaries would have sufficient notification of the new OEP and its timeframe through the 2019 Medicare & You handbook, *Medicare.gov* and member materials.

[xxii] The Center for Medicare Advocacy submitted comments encouraging CMS to consider eliminating IRE notices instead of eliminating the MA plan notice which would be more timely and more recognizable to a beneficiary. The Center pointed out that the burden could not be that substantial considering the notice from the plans is a model notice designated for that specific situation.

[xxiii] CMS disagreed with the Center and other advocacy organization comments, but did state that they would continue to work closely with the IRE through their contract oversight to make sure that Medicare beneficiaries receive timely notice from the IRE.

[xxiv] According to CMS, for example, "a beneficiary who is determined to be at-risk based on the clinical guidelines that look at the beneficiary's opioid use could have a coverage limitation applied under a drug management program to both opioids and benzodiazepines to manage current and future concurrent use. For example, a sponsor could require an at-risk beneficiary to obtain both opioids and benzodiazepines from one selected pharmacy." 83 Fed Reg 16446.

[xxv]83 Fed Reg 16465.

[xxvi] See the discussion in the preamble to the final rule concerning the first notice identifying the plan's intent to designate the individual as at-risk when no limitations have been imposed so the "situation is not ripe for appeal." 83 Fed Reg 16473.

[xxvii] As justification for limiting the SEP rights of duals/LIS individuals, CMS notes that "more than 76 percent of all beneficiaries estimated to be potential at-risk beneficiaries are LIS-eligible individuals." 83 Fed Reg 16464.

[xxviii] See discussion at 83 Fed Reg 16474 – 76 re: scope of appeal rights.

[xxix]The Center for Medicare Advocacy submitted comments encouraging CMS to keep the existing deadline for plan sponsors and the IRE based on the impact this change could have on beneficiaries. A beneficiary with a limited budget could be forced to forego making further purchases of the same drug as they await a decision which could have an adverse effect on their health. The Center also asserted that it is conceivable that a beneficiary, while waiting for a redetermination or IRE reconsideration, may still have to pay for the Part D drug that is the subject of the appeal and may use the information from the decision(s) to make an informed consumer decision whether they will need to plan to pay for the drug out of pocket again or get a prescription for an alternative drug.

As expected, in the final regulations, CMS noted that they received many comments, primarily from plans, expressing support for the proposed change. CMS ultimately justified the change with the explanation that giving more time to the plan will result in a more thorough review of the payment request which "may" lead to fewer unfavorable decisions due to insufficient information to support the request. CMS also noted that giving the plans more time for payment requests will allow the plans to prioritize appeals dealing with coverage where the beneficiary has not yet obtained the drug which they considered to be more time-sensitive.

Also as expected, in finalizing this proposed change, CMS gave short shrift to the Center for Medicare Advocacy and other beneficiary advocacy groups' comments expressing concern for the impact this could have on individual enrollees. CMS feels that the advantages offset any additional wait time for a beneficiary and that an additional 7 calendar days to receive notice on a payment request poses minimal to no risk of adversely affecting the health of an enrollee who has requested reimbursement. CMS only sees the additional 7 calendar days as a positive for beneficiaries because decisions regarding payment are more likely to be better informed which in turn would "potentially" result in fewer payment decisions being denied and subject to further appeal.

[xxx] CMS Press Release entitled "CMS Finalizes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-F)" (April 2, 2018), available at: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-policy-changes-and-updates-medicare-advantage-and-prescription-drug-benefit-program.

[xxxi]The Center for Medicare Advocacy urged CMS not to eliminate the enrollment requirements which provide important protections for Medicare beneficiaries. As CMS pointed out in the proposed regulations, the process of applying for Medicare enrollment "is the most thorough means of confirming a provider's compliance with Medicare requirements…" The Center pointed out that scrapping enrollment requirements for a preclusion list was reactive rather than proactive and could lead to continuity and access to care issues that CMS failed to address.

In the final regulations CMS admitted that requiring provider enrollment creates more robust data but, "wanting to reduce as much burden as possible for providers", ultimately concluded that the preclusion list approach would provide sufficient program safeguards that would balance program integrity initiatives, provider burden, and any concerns regarding potential access to care issue. CMS justified replacing provider enrollment requirements with a preclusion list by noting that they had already completed a vigorous Part D and MA enrollment campaign yet the number of unenrolled prescribers and providers remained high, thus potentially creating significant access to care issues. The Center commented, expressing concerns for continuity of care and access to care issues for someone who is a patient of a provider not enrolled in Medicare, who disenrolls from the MA plan and elects traditional Medicare. That beneficiary would no longer be able to receive services from their regular physician and have them billed to traditional Medicare. CMS indicated they were not aware of this as a significant issue and they expected MA enrollees to appropriately assess whether their health care providers are in a network of available providers when selecting among Medicare coverage options. Ultimately they felt that beneficiaries should be able to ask the necessary questions of a treating provider when contemplating whether to switch to original Medicare for coverage.