

February 13, 2023

Submitted Electronically via www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4201-P)

Dear Administrator Brooks-LaSure:

The Center for Medicare Advocacy (the Center) is a national, non-profit law organization that works to ensure access to Medicare, health equity, and quality healthcare. The organization provides education, legal assistance, research and analysis on behalf of older people and people with disabilities, particularly those with long-term conditions. The Center's policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues. Additionally, the Center provides individual legal representation and, when necessary, challenges patterns and practices that inappropriately deny access to Medicare and necessary care. We appreciate the opportunity to submit these comments to the above-referenced rule.

Introduction/Overview

We commend CMS for demonstrating, through this rule, a renewed interest in strengthening consumer protections and providing increased oversight of Medicare Advantage (MA) and Part D plans. After many years of regulatory neglect of the MA program, we applaud the proposals in this rule, particularly concerning MA prior authorization and marketing issues, which are the topics we predominantly focus on in our comments below. We note that effectuating CMS' intent as demonstrated through this proposed rule will come down largely to enforcement. As enrollment in MA crosses the 50% threshold, we are concerned that CMS/HHS has not reallocated resources accordingly. We urge CMS to seek additional funding from Congress to support enhanced oversight efforts. We also urge stronger support and more funding for the State Health Insurance Assistance Programs (SHIPs) as a source of free, unbiased assistance to Medicare beneficiaries. In addition, further efforts are needed both at the congressional and administrative level to rebalance the unlevel playing field between traditional Medicare and MA.

Before providing our comments to provisions of the proposed rule, we outline some of the additional, unaddressed steps we urge CMS to take in order to ensure adequate oversight of plans and consumer protections.

Unaddressed Issues

We appreciate CMS' solicitation of information concerning Medicare Advantage (MA) plans in last year's Request for Information (RFI). Many of the issues below were raised in the Center's RFI comments;¹ others are long-standing issues we and others have addressed elsewhere. We urge CMS to consider the following:

- Further Strengthen Medicare Advantage Network Adequacy Requirements

We appreciate and support CMS' proposals in section III.B of this rule, including the network adequacy enhancements regarding providers of behavioral health services. However, CMS must, among other things, reinstate the requirements as they were prior to being weakened by provisions of CMS' final 2021 Part C & D rule. In addition, in order to improve access to acute and post-acute care for MA enrollees, we urge CMS to include inpatient rehabilitation facilities (IRFs), comprehensive outpatient rehabilitation facilities (CORFs), and long-term acute care hospitals (LTCHs) in the list of facility-specialty types that are subject to MA network adequacy evaluations per 42 CFR §422.116(b)(2).

- Reinstate Medicare Advantage Meaningful Differences Requirements and Impose a Limitation on the Number of Plan Offerings

As discussed in our RFI comments, the increasingly complex and over-saturated Medicare marketplace is becoming more difficult for consumers to navigate. In 2023, the typical beneficiary has a choice of 43 Medicare Advantage plans and 24 Part D prescription drug plans.² The erosion of MA uniformity standards and meaningful difference requirements in recent years have made informed choice more, not less, difficult. In order to improve informed decision-making in Medicare, we urge CMS to import some of the standardization of plan benefits, limitations on issuer plan offerings and other elements of the Marketplaces into Medicare Advantage.

- Overhaul Agent and Broker Commissions

As discussed in comments to the marketing provisions below, wildly disparate commissions paid for MA plan enrollment vs. Part D enrollments helps drive those seeking commissions to push people towards MA plans, even if that is not the best option for them.³ Further, as we suggested in our comments to CMS' RFI, we urge CMS to require agents and brokers to disclose commissions they receive for the sale of a given product so that individuals have a better understanding of incentives behind sales pitches. We also urge CMS to establish other consumer protections concerning marketing, as further outlined in our comments to the marketing section below.

¹ See CMA Comments to CMS' RFI re: MA (August 31, 2022), available at: <https://medicareadvocacy.org/wp-content/uploads/2022/09/MA-RFI-Comments-2022.pdf>

² Kaiser Family Foundation, "Medicare Advantage Spotlight: First Look" (Nov. 2022), available at: <https://www.kff.org/medicare/issue-brief/medicare-advantage-2023-spotlight-first-look/>.

³ Also see, e.g. discussion of commissions in *CMA Alert* "Senate Report Highlights Widespread Medicare Advantage Marketing Misconduct – But the Driving Forces of Misconduct Are Broader" (Nov. 10, 2022): <https://medicareadvocacy.org/ma-misconduct/>.

Comments to Specific NPRM Provisions

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018, the Consolidated Appropriations Act, 2021, and the Inflation Reduction Act of 2022

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

We appreciate CMS’ efforts to address the proliferation of D-SNP Look-Alike plans, and we support the proposals to close unforeseen loopholes in the scope of the regulation. We urge CMS to use its discretion to lower the current threshold of a plan’s total enrollment of those entitled to Medicaid in order to non-renew a contract with a non-SNP MA plan from 80% to 50%.

B. Part D Special Enrollment Period Change Based on CAA Medicare Enrollment Changes (§ 423.38)

We support CMS’ proposal “to revise the start and end date for the SEP for Individuals Who Enroll in Part B During the Part B GEP to align with the Part B entitlement dates for someone who enrolls in Part B using the GEP that starts January 1, 2023. Accordingly, we are also proposing to revise the effective date of the individual’s Part D plan enrollment, which is always July 1st under the current parameters of this Part D SEP.” We agree that this change will simplify the enrollment process and reduce potential gaps in drug coverage.

C. Alignment of Part C and Part D Special Enrollment Periods with Medicare Exceptional Condition Enrollment (§§ 422.62 and 423.38)

CMS proposes to add corresponding exceptional condition SEPs for MA and Part D enrollment to align with the new Medicare premium Part A and B exceptional condition SEPs. The SEPs would begin when the individual submits the application for premium Part A and Part B, or only Part B, and continue for the first 2 months of enrollment in Part A (premium or premium-free) and Part B and the enrollment would be effective the first of the month following the month the MA or Part D plan receives the enrollment request. We support this proposal.

D. Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LINET) Program (§§ 423.2500 through 423.2536)

We support all of the proposals outlined to implement LINET program changes. We appreciate CMS’ work to sustain this critical program for low-income beneficiaries.

E. Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program (§§ 423.773 and 423.780)

We strongly support implementation of the Inflation Reduction Act provision that will provide the full LIS subsidy for those who currently qualify for the partial subsidy. We urge CMS to actively educate beneficiaries about this pending change in 2024 and accompany such efforts with actively promoting enrollment in Medicare Savings Programs.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

3. Medicare Advantage (MA) Provider Directories (§ 422.111)

Section 1852(c)(1) of the Social Security Act requires that MA organizations must provide each enrollee with a detailed description of plan provisions – including plan providers – in a clear, accurate, and standardized form. Historically, CMS has interpreted the disclosure requirement at § 422.111(b)(3)(i) – “the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services” – as referring to the provider directory. In addition to requiring provider directory data elements, CMS is addressing best practices for provider directories. This includes encouraging organizations to identify non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities. CMS is proposing to codify these two best practices as a regulatory requirement at §422.111(b)(3)(i). If finalized, CMS intends to monitor organization compliance with the proposed new requirements through periodic online provider directory reviews, as CMS deems necessary.

Furthermore, to enhanced requirements for MA provider directories in the area of behavioral health, CMS proposes to add a new required provider directory data element for certain providers who offer medications for opioid use disorder (MOUD). CMS proposes to require organizations to identify certain providers in the provider directory who have obtained a waiver under section 303(g)(2) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)(2)(B)(i)-(ii) from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) to treat patients with MOUD and who are listed on SAMHSA’s Buprenorphine Practitioner Locator (BPL). CMS stresses that the new proposed provider directory data element is important and necessary for ensuring access to behavioral health services for MA enrollees. If finalized, CMS intends to monitor organization compliance with the proposed new requirements through periodic online provider directory reviews, as CMS deems necessary.

Recommendations

The Center supports codifying that organizations must identify non-English languages spoken by each provider and provider/location accessibility for people with physical disabilities as regulatory requirements to § 422.111(b)(3)(i).

We also support requiring organizations to identify MOUD-waivered providers, which would allow MA enrollees to use their provider directories to search for providers who have special training to provide MOUD and are allowed to administer, dispense, or prescribe medications in an office setting.

According to the latest U.S. Census bureau statistics, over one-in-five people speak a language other than English in their home.⁴ Individuals with limited English proficiency – defined as having English as a second language and possessing limited ability to read, write, speak, and understand the English language⁵ – are at a risk for experiencing health care disparities in both accessing health care and screenings.⁶

Furthermore, about 1.7 million Medicare beneficiaries have a diagnosed substance abuse disorder (SUD)⁷ and 25% of beneficiaries have a mental health (MH) condition.⁸ A staggering 93% of Medicare beneficiaries ages 65 and older with a SUD, however, do not receive treatment.⁹ While an estimated one in three beneficiaries 65 and older do not receive treatment with MH needs.¹⁰

We offer the following recommendation regarding CMS’s monitoring of an organization’s compliance with the proposed requirements.

⁴ U.S. Census Bureau. *Language Spoken at Home*. Census.gov. (March 8, 2022). Available at: <https://www.census.gov/acs/www/about/why-we-ask-each-question/language/>

⁵ Foiles Sifuentes AM, Robledo Cornejo M, Li NC, Castaneda-Avila MA, Tjia J, Lapane KL. The Role of Limited English Proficiency and Access to Health Insurance and Health Care in the Affordable Care Act Era. *Health Equity*. 2020 Dec 11;4(1):509-517. doi: 10.1089/heq.2020.0057. PMID: 33376934; PMCID: PMC7757700.

⁶ Smith, Diane L. (2009) "Health Care Disparities for Persons with Limited English Proficiency: Relationships from the 2006 Medical Expenditure Panel Survey (MEPS)," *Journal of Health Disparities Research and Practice*: Vol. 3: Iss. 3, Article 4, available at: <https://digitalscholarship.unlv.edu/jhdrp/vol3/iss3/4>

⁷ William J. Parish, Tami L Mark, Ellen M Weber, Deborah G Steinberg, "Substance Use Disorders Among Medicare Beneficiaries: Prevalence, Mental and Physical Comorbidities, and Treatment Barriers" *Am J Prev Med*. 2022 Aug;63(2):225-232. doi: 10.1016/j.amepre.2022.01.021. Epub 2022 Mar 21, available at: <https://pubmed.ncbi.nlm.nih.gov/35331570/>.

⁸ Commonwealth Fund, "Medicare’s Mental Health Coverage: How COVID-19 Highlights Gaps and Opportunities for Improvement" (July 2020), available at: <https://www.commonwealthfund.org/publications/issue-briefs/2020/jul/medicare-mental-health-coverage-covid-19-gaps-opportunities>.

⁹ Parish, *supra* note 1.

¹⁰ US Department of Health and Human Services/Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, "Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020" *MMWR* / July 22, 2022 / Vol. 71 / No. 29, available at: <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7129e2-H.pdf>.

Specify and Concretize Language around Monitoring Compliance of Proposed Requirements

As proposed, CMS intends monitor organization compliance with the proposed new requirements through periodic online provider directory reviews, as CMS deems necessary. This language is ambiguous and does not provide transparency into the regularity in which CMS will be monitoring the organizations.

- We urge CMS to provide specific and concrete timelines regarding both the implementation of the requirements and the monitoring of them. We believe this will provide greater incentives for the MA organizations to update directories, and will also provide the public with a clear expectations around when the information will be available to them.

This recommendation should be implemented in light of challenges CMS has encountered with ensuring accurate provider information. A U.S. Government Accountability Office (U.S. GAO) report published in 2015 found that lack of regular review of Medicare Advantage Organizations (MAOs) meant that CMS could not be assured that MAO networks were providing adequate and sufficient access for enrollees.¹¹ In the report, the GAO found that as of June 2022 CMS still had not implemented its 2015 recommendations of taking steps to verify the accuracy of provider network information submitted by MAOs.¹²

- We recommend CMS use the terms “mental health and substance use disorder” rather than “behavioral health” to ensure that MA plans contract with providers who specialize in each of these conditions and do not focus on one to the exclusion of the other. Additionally, this change will ensure programs for coordination of plan services with community and social services are available for both conditions.

Ensure Accuracy of Directories

Medicare Advantage plan directories have been notorious for containing inaccuracies. According to a 2018 CMS report, almost half (48.7%) of the Medicare Advantage provider directories contained inaccuracies.¹³

- We urge CMS to ensure that directories are accurate. Otherwise, it negates the purpose and benefit of this requirement. Furthermore, any errors in inclusion of this information

¹¹ U.S. Government Accountability Office. *Medicare Advantage: Actions Needed to Enhance CMS Oversight of Provider Network Adequacy*. GAO-15-710. (August 2015). Available at: <https://www.gao.gov/products/gao-15-710>

¹² U.S. Government Accountability Office. *Medicare Advantage: Continued Monitoring and Implementing GAO Recommendations Could Improve Oversight*. GAO-22-106026. (June 2022). Available at: <https://www.gao.gov/assets/gao-22-106026.pdf>

¹³ CMS. *Online Provider Directory Review Report*. (November 28, 2018). Available at: https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Round_3_11-28-2018.pdf

directly target and impact the most vulnerable within the Medicare population. Thereby, directly counteracting CMS’s first strategic pillar of health equity.¹⁴

4. Digital Health Education for Medicare Advantage (MA) Enrollees Using Telehealth (§ 422.112)

According to a report by the Assistant Secretary for Planning and Evaluation, the number of Medicare beneficiaries accessing telehealth visits increased from 840,000 in 2019 to almost 52.7 million in 2020, amounting to an increase of over 6,000%.¹⁵

CMS recognizes that equity in telehealth is difficult to attain due to barriers to telehealth access. Those barriers may include lack of access to technology, lack of housing or private space to participate in virtual visits, language barriers, and lack of adaptive equipment. During the height of the pandemic, 52% of Area Agencies on Aging (AAAs) reported that they saw limited or no access to technology as being one of the greatest challenges facing older adults.¹⁶

The Center for Medicare Advocacy conducted its own interviews with AAAs around the country and found three key barriers to access to telehealth services for Medicare beneficiaries: improper or lack of access to proper equipment on a stable platform, accessibility challenges including issues around broadband, and the need for expanded training options targeted to teach beneficiaries how to use their equipment to access telehealth services and health portals.¹⁷

CMS is proposing to implement regulations addressing digital health literacy in MA programs in an effort to help underserved communities in need of assistance to improve their digital health literacy and help advance the goal of achieving health equity. CMS proposes to add requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist them with accessing any medically necessary covered health benefits. Specifically, CMS is seeks comment on whether to amend § 422.100 instead of § 422.112(b) in order to apply this new requirement to all MA plans and not just coordinated care plans.

Recommendations

In a 2021 interview with the *Washington Post*, Health and Human Services Secretary Xavier Becerra spoke about the importance of telehealth moving forward and the need to prevent the increase in disparities for Medicare beneficiaries. “Technology is so much of the ballgame these

¹⁴ CMS. *CMS Strategic Plan Pillar: Health Equity*. (2022). Available at: <https://www.cms.gov/files/document/health-equity-fact-sheet.pdf>

¹⁵ St. John, C. *Report: Telehealth Use by Medicare Beneficiaries Increases Over 6,000% in 2020*. Center for Medicare Advocacy. (December 9, 2021). Available at: <https://medicareadvocacy.org/report-telehealth-use-by-medicare-beneficiaries-increases-over-6000-in-2020/>

¹⁶ 4 National Association of Area Agencies on Aging. *The Continued Impact of COVID-19 on Area Agencies on Aging and Their Clients in 2021*. (2021). Available at: <https://www.usaging.org/Files/n4aFast%20Facts%202021%20COVID-508.pdf>

¹⁷ St. John, C. *Telehealth and the Medicare Population: Building a Foundation for the Virtual Health Care Revolution*. Center for Medicare Advocacy. (May 2022). Available at: https://medicareadvocacy.org/wp-content/uploads/2022/05/Telehealth-Report_CMA_final.pdf

days ... But we have to make sure we use the technology the right way as well. We can't leave people behind simply because they can't afford the technology or the technology hasn't reached where they live. We want to make sure everyone benefits.”¹⁸

The populations Medicare serves include those who are most vulnerable to the impacts of disparities. These vulnerable populations must navigate a complicated web of issues impacting access to telehealth services, including age-related physical issues, having proper equipment and broadband access, being able to operate that equipment, language barriers, and having enough health literacy to be able to properly communicate needs to the providers.

Purposeful, Mandatory, and Coordinated Action in Areas Beyond Digital Health Education

While the Center supports this proposal, the solution requires purposeful and mandatory action in areas beyond simply attention to digital health education. Additionally, while CMS acknowledges that geographic location (e.g., rural communities) and persistent poverty limit access to modern communication technologies, we urge cross-agency coordinated action (for example with the Federal Communications Commission) to work to improve barriers to access telehealth services, thereby helping to bridge the digital divide. We offer in-depth illustrations of the impacts of these disparities in our report *Telehealth and the Medicare Population: Building a Foundation for the Virtual Health Care Revolution*.

Joan Marshall, Respite Program Coordinator at Connecticut's Senior Resources Agency explained in an interview with the Center, “It's those people who don't have anyone – who don't drive, who don't understand the internet, who don't have a computer, who don't really want a smartphone, don't have someone to help ... those are the people that are just going to be completely left out of the picture, and are the hardest to reach and probably would benefit the most.” Despite challenges like this, improvement is possible and within reach with purposeful and coordinated action. According to Research Scientist, Dr. Chaiwoo Lee, at the MIT AgeLab, “I think we're probably looking at a near future where it might not be too much of an issue for older adults to use smartphones, because of the demographic trend or technological trend, and also the phones are being improved themselves with different accessibility features.”¹⁹

The digital divide can reflect multiple, layered issues. According to the U.S. Census Bureau, lower levels of broadband connectivity are associated with households that rent rather than own a home, households with limited English proficiency, and households with at least one person who is disabled.²⁰

¹⁸ Washington Post Live. Transcript: Digital Health with Xavier Becerra, John Brownstein, Phd, Tufia C. Haddad, MD, and Jack Resneck Jr., MD. The Washington Post. (June 24, 2021). Available at: <https://www.washingtonpost.com/washington-post-live/2021/06/24/transcript-digital-health-with-xavier-becerrajohn-brownstein-phd-tufia-c-haddad-md-jack-resneck-jr-md/>

¹⁹ St. John, *supra* note 12.

²⁰ U.S. Census Bureau. Computer and Internet Use in the United States: 2018. Census.gov. (April 21, 2021). Available at: <https://www.census.gov/newsroom/press-releases/2021/computer-internet-use.html>

- We urge CMS to apply this requirement to all MA plans and not limit it coordinated care plans. Therefore, we agree that § 422.100 (General Requirements) should be amended instead of § 422.112(b).

Multiple Language Educational Platforms

After the MA organization determines which enrollees are experiencing low digital health literacy, CMS proposes the MA organization would then have to offer a digital health education program to these enrollees.

The Curry Senior Center in San Francisco, California serves a population of older adults that speak a wide variety of languages. Health Educator Terrie Li, at the Curry Senior Center, spoke about challenges she has seen with older adults who have limited English proficiency accessing telehealth services. “Even if they are able to get online, most of the systems that support telehealth, such as hospital portals and video visits are hard to access for people who speak other languages. Clients find it difficult to interpret test results because it’s all written in English. They can only depend on the graphic (recommended range) to understand whether they are in the “green/healthy” range.”²¹

- We urge CMS to require digital health education to be offered in multiple languages to increase access to non-English proficient beneficiaries.

Clarify Terminology

- We urge CMS to carefully define terms to ensure clarity between digital literacy, health literacy, health insurance literacy, and other aspects that impact a beneficiary’s understanding of benefits, diagnoses, treatment options, modalities for accessing care, and other issues.

Transparency to CMS and the Public

In order to monitor the impact of the proposed requirement for digital health literacy screening and digital health education programs, CMS proposes to require MA organizations to make information about these programs available to CMS upon request. Requested data may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manners(s) or method(s) of digital health literacy screening and digital education, financial impact of the program on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance. The purpose of requiring MA organizations to make such information available would be to identify best practices for improving digital health literacy amongst MA enrollees and to determine whether CMS should make improvements to the regulation and/or guidance regarding this requirement. Overall, the Center supports the above proposal with the following recommendations:

²¹ St. John, *supra* note 12.

- We urge CMS to require the above information to be reported to CMS at a minimum of every six months, rather than “upon request” by CMS. This would affirm CMS’s stated desire to ensure the ability to identify best practices for improving digital health literacy and ensure accountability both from the MA plans and from CMS.
- We urge CMS to require the above information to be available to the public and posted on the agency's website. Researchers, policy makers, and beneficiaries have the right to access this information, since the MA plans are funded by the government with taxpayer money. The data should be utilized not only to ensure best practices for improving digital health literacy, but also to advance policy initiatives.

B. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116)

2. Behavioral Health Specialties in Medicare Advantage (MA) Networks

Currently, MA organizations are required to demonstrate that they meet network adequacy for two behavioral health specialty types, psychiatry and inpatient psychiatric facility services. CMS proposes to add three new provider specialty types: (1) clinical psychology, (2) clinical social work, and (3) Prescribers of Medication for Opioid Use Disorder. We strongly support these proposals. Establishing these network adequacy standards for Prescribers of MOUD will both incentivize MA plans to offer more favorable network contracts to opioid treatment programs (OTPs) and increase access to this evidence-based standard of care for all Medicare beneficiaries.

CMS proposes to add travel time and distance standards for the new provider categories. We support the addition of such standards and recommend that that the standards mirror those used for primary care physicians to increase access to these vital services and to reduce disparities between physical and behavioral health care services. MOUD services in particular often require frequent, sometimes daily, visits.

CMS proposes to amend the list of health care providers in the existing access to services standards to include providers that specialize in behavioral health services. We strongly support this proposal.

CMS proposes to add all the new behavioral health specialty types to the list of the specialty types that that will receive the credit if the MA organization’s contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits. We oppose this proposal and reiterate our position that it is inappropriate to allow a credit for telehealth. Enrollees must not be shunted into telehealth with no in-person options, and MA plans must not be permitted to shortchange network adequacy in any way.

3. Behavioral Health Services in Medicare Advantage (MA)

CMS proposes to add behavioral health services to the types of services for which MA organizations must have programs in place to ensure continuity of care and integration of services. CMS also proposes to add language to definitively clarify that an emergency medical condition can be physical or mental in nature. We strongly support these proposals.

4. Medicare Advantage (MA) Access to Services: Appointment Wait Time Standards

CMS proposes to codify appointment wait times as standards for primary care services that are the same as the appointment wait times described in the Manual and to extend those standards to behavioral health services. We support this proposal. We encourage CMS to separate out mental health and substance use disorder services for this metric to ensure they can be tracked separately to ensure sufficient and timely access to both. We agree that MA plans should be required to achieve the appointment wait time metrics for each service type for a minimum of 95% of plan enrollees.

C. Medicare Advantage (MA) Network Adequacy: Access to Services (§ 422.112)

CMS proposes to more clearly state the scope of the MA organization's obligation to ensure adequate access to medically necessary covered benefits by requiring MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. We strongly support this proposal and urge CMS to require plans to clearly and prominently highlight this requirement in plan materials, including the EOB. This provision is particularly important for individuals with rare conditions for which the pool of experienced providers is relatively small. We urge CMS to track MA enrollees' appeals of requests for obtaining services out-of-network in order to better identify plans that are not following this rule.

As noted above in our introductory comments, we urge CMS to generally strengthen MA network adequacy rules, including to improve access to acute and post-acute care for MA enrollees. Specifically, we urge CMS to include inpatient rehabilitation facilities (IRFs), comprehensive outpatient rehabilitation facilities (CORFs), and long-term acute care hospitals (LTCHs) in the list of facility-specialty types that are subject to MA network adequacy evaluations per 42 CFR §422.116(b)(2).

D. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

CMS proposes more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. Given the significant disruptions in care that can result from provider contract terminations, we strongly support the proposed changes. In particular, the proposals to impose more stringent requirements regarding "no cause" terminations, the expansion of the population of affected individuals who are patients of behavior health providers, and the requirement of both written and telephonic notice for these providers where disruption is particularly challenging. In our experience, beneficiaries are often completely caught off guard when they find that their provider is no longer in network mid-year and it is extremely disruptive to their course of care.

CMS also solicits comment on its proposal to consider an enrollee who is impacted by a provider contract termination to be someone who is experiencing an exceptional condition, or on alternative approaches. As we stated in our comments to CMS' MA RFI, CMS should strengthen consumer protections surrounding MA plan mid-year provider network terminations. The most effective way to protect consumers from being trapped in their plans after their own doctors are involuntarily terminated is to prohibit MA plans from terminating network providers mid-year without cause. We urge CMS to strengthen or otherwise expand the right to a limited special enrollment period (SEP), which is only available to beneficiaries affected by "significant" network terminations (42 CFR §422.62(b)(23)). Availability of this SEP for loss of access to a terminated provider should not hinge upon an unspecified number of additional individuals similarly impacted; rather, it should be available to plan enrollees who wish to continue to see their provider(s) by changing plans mid-year. In addition, the availability of this limited SEP right is not adequately expressed in beneficiary-oriented materials, including those issued by plan sponsors (e.g. the Annual Notice of Change) or by CMS (e.g. *Medicare & You* and the www.medicare.gov website).

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

Overarching Comments

Medicare Advantage (MA) plans are entrusted with managing and providing for the health and wellbeing of their enrollees. Prior authorization (PA), a form of utilization management, is often touted by plans as a means of ensuring that enrollees do not receive unnecessary care. All too often, however, PA is used as a means to deprive enrollees of medically necessary care and services. Services and items that would be covered in traditional Medicare are routinely denied by MA plans. We applaud CMS for confronting the issue of the inappropriate use of prior authorization by MA plans. It is clear that the agency has listened to stakeholders' concerns, including consumer advocacy organizations such as ours, and is trying to make the process work better for all MA enrollees. We want to help CMS achieve this goal, and offer suggestions below regarding how to effectuate CMS' stated intent.

Our experiences concerning MA enrollees' barriers to care are confirmed in two HHS Office of Inspector General (OIG) reports, one in 2018²² that found "widespread and persistent problems related to denials of care and payment in Medicare Advantage' plans". The report's findings included that when beneficiaries and providers appealed preauthorization and payment denials, MA plans "overturned 75 percent of their own denials." At the same time, "beneficiaries and providers appealed only 1 percent of denials to the first level of appeal." As noted in the proposed rule, OIG issued another report in 2022²³ that analyzed denials issued by 15 of the

²² HHS OIG "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials" (September 2018), available at: <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf>.

²³ HHS OIG "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), available at: <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>.

largest MA plans during one week in June 2019. Among the prior authorization requests denied by MA plans, OIG found that 13 percent met Medicare coverage rules – “in other words, these services likely would have been approved for these beneficiaries under original Medicare.” With respect to payment requests denied, OIG found that 18 percent met Medicare coverage rules and MA billing rules.

More recently in February 2023, the Kaiser Family Foundation issued a study²⁴ analyzing the volume of Medicare Advantage prior authorization requests and approvals in 2021. The report found that 6% of MA prior auth requests were denied in full or in part. Overall, just 11% of denied prior auth requests were appealed; of those that were appealed, 82% resulted in the initial denial being either fully or partially overturned. Kaiser noted:

The high frequency of favorable outcomes upon appeal raises questions about whether a larger share of initial determinations should have been approved. Alternatively, it could reflect initial requests that failed to provide necessary documentation. In either case, medical care that was ordered by a health care provider and ultimately deemed necessary was potentially delayed because of the additional step of appealing the initial prior authorization decision, which may have negative effects on beneficiaries’ health.

Greater Oversight of MA Plans and Medicare Contractors Needed

In order to ensure that MA plans comply with Medicare guidelines, including those proposed in this rule, there are a number of related factors beyond the scope of the proposed rule that must be addressed. In short, without adequate oversight and enforcement, nothing will change. As it stands now, enforcement of MA rules is largely done by beneficiaries themselves via the appeals process. As noted above, though, only a fraction of MA enrollees who are denied care actually appeal, meaning that most inappropriate denials or terminations of care by MA plans goes unchallenged, let alone punished. We urge CMS to step up oversight, including monitoring the under-provision of care (not just over-provision, as in traditional Medicare). If it has not done so already, CMS should implement the recommendations made by OIG in their 2018 and 2022 reports (referenced above), including: “examining particular service types, including adding aggravating factors in civil money penalty calculations if MAO denials resulted in beneficiaries’ not being able to access needed services, and considering additional enforcement actions for MAOs that demonstrate a pattern of inappropriate payment denials” (2022); and “Enhance its oversight of MAO contracts, including those with extremely high overturn rates and/or low appeal rates, and take corrective action as appropriate” (2018).

In addition, CMS should increase oversight of Medicare contractors, including the Quality Improvement Organizations (QIOs) and Independent Review Entities (IREs) that handle external review of MA appeals. Along with the Medicare Administrative Contractors (MACs) in traditional Medicare, we find that these contractors routinely issue incomplete and/or incorrect opinions and sometimes misapply or misinterpret the law, often to the detriment of Medicare beneficiaries seeking medically necessary, covered services. Extensive oversight and training of these contractors is required, as well as further training of Office of Medicare Hearings and

²⁴ Kaiser Family Foundation, “Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021” (February 2023), available at: <https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/>.

Appeals' (OMHA) cadre of Administrative Law Judges (ALJs) and the Departmental Appeals Board (DAB) on Medicare coverage guidelines and MA plans' obligations to follow them.

Further, if the "Improving Seniors' Timely Access to Care Act" (H.R. 3173 in the last Congress) is not enacted, CMS should explore similar changes within its authority to accelerate MA organization determination deadlines (as is contemplated in CMS' Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (CMS-0057-P)). In addition, CMS should boost MA plan's data collection requirements, and in turn publish this data. As noted in the February 2023 Kaiser Family Foundation report cited above, "we were not able to analyze prior authorization rates by type of service or type of plan because CMS does not collect or report this information."

Enhanced Notice Requirements and Oversight

One of the findings of the 2018 OIG report, in addition to a high rate of inappropriate clinical decisions made by MA plans, was that MA plans were responsible for "insufficient denial letters issued to beneficiaries and providers" and engaged in "insufficient outreach before issuing denials". The report referenced CMS' own audits of plans in 2015 that "cited 45 percent of contracts for sending denial letters with incomplete or incorrect information, which may inhibit beneficiaries' and providers' ability to file a successful appeal." All too often, when MA plans deny or terminate care, across care setting, service, or item, they provide minimal, conclusory statements without justification. Statements such as "doesn't meet Medicare coverage guidelines" or "not medically reasonable and necessary" gives plan enrollees and providers little information as to why services are denied or prematurely terminated.

In traditional Medicare, there is outside and independent oversight of provider decision-making by Medicare Administrative Contractors (MACs) via claims processing. In the Medicare Advantage program, there is no such routine oversight unless beneficiaries choose to appeal (most of whom do not do so, as highlighted by the OIG and Kaiser reports referenced above). **The burden must be on the plan to "show their work" and adequately justify why Medicare rules are not met. We therefore urge CMS to strengthen written notice requirements that MA plans must follow both when they deny care and when they terminate care that has been authorized.** Otherwise, we will continue to see routine, knee-jerk denials without justification, and MA enrollee due process rights will be thwarted.

When an MA plan denies, discontinues or reduces care, Medicare rules currently require plans to issue a Notice of Denial of Medical Coverage or Payment (Form CMS-10003-NDMCP), also known as the Integrated Denial Notice (IDN).²⁵ This form requires plans to "provide a specific and detailed explanation of why the medical services/items or Part B drug or Medicaid drugs were denied, including a description of the applicable Medicare (or Medicaid) coverage rule or applicable plan policy (e.g., Evidence of Coverage provision) upon which the action was based. A specific explanation about what information is needed to approve coverage must be included." In our experience, these outlined elements of denial notices are viewed by plans as suggestions rather than requirements. All too often, people do not have enough information as to why their

²⁵ CMS website at: <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/Integrated-Denial-Notice-Instructions-CMS-10003.pdf>.

request was denied, including whether additional information is needed in order to have the request granted, and whether there is a clear error on the face of the denial (in other words, the wrong service or medical condition is referenced) so most people simply give up and do not appeal. All too often, people only receive a telephone call or other notification, not a written notice.

According to the president of a care management firm in a recent letter to our organization about barriers to care faced by his clients enrolled in MA plans, “Notice of denial of continued care *never meets the standard* set by 422.624. I have never seen an MA Plan give two days’ notice. Further, they notify the facility, not the enrollee or their designate.” In addition, he states that “[t]he enrollee’s right to receive detailed information about why care is declined almost never meets the standard imposed by 442.626. The Notice of Non-Coverage or ‘cut letter’ does not give enough information for the client’s advocate, the son or daughter of the enrollee, to make a coherent argument for continued care.”

In addition to ramping up enforcement over plans to ensure they are both authorizing medically necessary care and providing adequate notices, CMS should enhance existing notice requirements. In order to better ensure that plans are providing the required information, we urge CMS to standardize MA denial forms in a manner that makes it more clear what information is required, and, correspondingly, makes it more clear when an MA plan has failed to provide the required information. For example, under current Medicare rules (in both traditional Medicare and MA), home health agencies, (HHAs), skilled nursing facilities (SNFs), hospice agencies and comprehensive outpatient rehabilitation facilities (CORFs) must provide a A Detailed Explanation of Non-Coverage (DENC) to a beneficiary only if a beneficiary requests an expedited determination after receiving a Notice of Medicare Non-Coverage (NOMNC) when previously approved services are being terminated. The DENC requires the provider and/or plan to explain the specific reasons for the end of covered services,²⁶ including the following prompts:

We have reviewed your case and decided that Medicare coverage of your current {insert type} services should end.

- The facts used to make this decision:
- Detailed explanation of why your current services are no longer covered, and the specific Medicare coverage rules and policy used to make this decision:
- Plan policy, provision, or rationale used in making the decision (health plans only):

[Note that the form also prompts the recipient to request a copy of the policy or coverage guidelines used to make the decision in question, if desired.]

In order to better ensure that MA plans actually do more than a cursory, perfunctory review of a request for covered services, a detailed notice and explanation of non-coverage should be required upfront, and designed in a manner to ensure that plans fill in the required data elements. The scope of information required in the DENC should be the default when initial denials (via prior authorization) are issued as well as notices of termination of previously approved services,

²⁶ See <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-Expedited-Determination-Notices>.

regardless of whether a beneficiary chooses to appeal. This should be the standard across all care settings and services. This should not be considered a new “administrative burden” for plans, since (in theory) this type of review should already be happening when requests for coverage are made, and is already required under Medicare rules (even if such rules are not routinely followed).

Coverage Criteria for Basic Benefits

We strongly support CMS’ proposal “to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare” (p. 79499). We applaud CMS for asserting that “when an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies” (p. 79500).

We also strongly support CMS’ proposal that “MAOs may only deny a request for Medicare-covered post-acute care services in a particular setting, if the MAO determines that the Traditional Medicare coverage criteria for the services cannot be satisfied in that particular setting.” (p. 79501). As discussed further below, we also urge CMS to provide guardrails for situations when an MA plan does authorize coverage, but not enough.

The Center for Medicare Advocacy has reason to believe that the OIG findings referenced above actually understate the extent to which MA plans deny or prematurely terminate care. This is based, in part, on the recent increase in MA plans’ contracting with care management firms that employ algorithmic coverage determination software or tools that, in our experience, appears to lead to shorter periods of coverage and more frequent terminations of care.²⁷

In our casework, we have witnessed a dramatic growth in MA plans’ use of proprietary, algorithm-driven coverage decision-making tools through naviHealth, MyNexus, CareCentrix, Milliman, InterQual and other third-party entities that plans contract with to make coverage decisions in certain care settings, including skilled nursing facilities and home health care. The required assessment of each individual patient’s needs has been replaced by “artificial” general rules of thumb, which are prohibited in Medicare coverage decisions.²⁸

One example of an MA plan contractor using inappropriate rules of thumb is a chart (on file with the Center) developed by myNexus and given to a home health agency that outlines what one MA plan will cover by specifying pre-determined home health visits by discipline. For example,

²⁷ See, e.g., Center for Medicare Advocacy publications: “The Role of AI-Powered Decision-Making Technology in Medicare Coverage Determinations” (January 2022), available at: <https://medicareadvocacy.org/wp-content/uploads/2022/01/AI-Tools-In-Medicare.pdf>; “When Artificial Intelligence in Medicare Advantage Impedes Access to Care: A Case Study” (April 21, 2022), available at: <https://medicareadvocacy.org/ai-plus-ma-equals-bad-care-decisions/>; Center for Medicare Advocacy Home Health Survey: Medicare Beneficiaries Likely Misinformed and Underserved (Dec. 2021) at: <https://medicareadvocacy.org/wp-content/uploads/2021/12/CMA-Survey-Medicare-Home-Health-Underservice.pdf>; and Report: Nursing Home MA Issues Survey (Aug. 2022) at: <https://medicareadvocacy.org/report-nursing-home-ma-issues-survey/>.

²⁸ See, e.g., 42 CFR §409.44; Medicare Benefit Policy Manual (MBPM) Ch. 7, Sec. 20.3; Medicare Program Integrity Manual (MPIM), Ch. 6, Sec. 6.1.

according to the chart, someone with COPD will get 5 skilled nursing visits, 6 PT visits, and 0 ST, OT, MSW and home health aide visits. This type of pre-determined coverage limitation violates Medicare rules on its face. **CMS should explicitly inform plans that use of such tools is prohibited under Medicare rules – even as “guidance” – as such limitations do not appear in any traditional Medicare law, regulations, sub-regulatory or other guidance.**

In addition to Medicare beneficiaries and consumer advocates, providers are increasingly expressing frustration about MA plans’ overly burdensome restrictions.²⁹ For example, a September 2022 article in *McKnights Long-Term Care News* stated that “seniors are often denied or delayed access to care they need as they become sicker and near the end of life, a provider complaint backed up by an OIG investigation. Skilled nursing facilities have found themselves fighting routine denials with no real way to fight back as MA dominance grows.”³⁰ A May 2022 article in the same publication noted that “[n]ot only are many [nursing facilities] seeing managed care plans increase payment denials, some observers say they’re often doing it without justifiable cause”; the article offers advice to facilities from a nursing home industry consultant that includes “creating an easy-to-follow cheat sheet to remind staff **which plans cover different therapy levels**, medications, and more” [emphasis added].³¹ We raise the obvious point that under no equitable and uniform interpretation of Medicare coverage guidelines should different MA plan sponsors “cover different therapy levels.” The fact that providers can tell the difference between what plans will routinely cover or deny what services points to severe, systemic and disparate access to care problems for MA enrollees. For MA enrollees, there is not currently “equal access to Part A and Part B benefits as provided in the Traditional Medicare program” (p. 79502).

Medicare requires an individualized assessment of each beneficiary’s qualification for coverage in certain care settings (for example, in skilled nursing facilities and home health care).³² Algorithmic tools employed by MA plans and their contractors, however, provide recommendations based on previous patient experiences that plans assert are just “guides” or “suggestions” for coverage, but which in our experience and that of providers are treated as immutable and inflexible determinations of coverage.

One example is naviHealth’s “Predict Reports” (sample on file with the Center) which are given to certain MA enrollees in a SNF and provide target discharge dates and therapy minutes defined at the outset of care and treated as determinative by MA plans’ care management firms. These are coverage decisions made by plan contractors at the outset of care, often without input from clinicians providing the actual care. If CMS wishes to effectuate its intended goal that “MA organization[s] cannot deny coverage of [an] item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies” then **the agency must explicitly articulate that the use of these algorithmic tools to make coverage**

²⁹ See, e.g., [CMA Alert](#) (May 5, 2022).

³⁰ “[‘Death spiral’ for SNFs as Medicare Advantage pay decreases](#)” by Kimberly Marselas, *McKnights Long-Term Care News* (Sept 6, 2022).

³¹ “[As Medicare Advantage grows, experts say, so do hard-to-fight denials](#)” by Kimberly Marselas, *McKnights Long-Term Care News* (May 19, 2022).

³² See, e.g., CMS. *Frequently Asked Questions (FAQs) Regarding Jimmo Settlement Agreement*. (Updated Dec. 1, 2021) Available at: <https://www.cms.gov/Center/Special-Topic/Jimmo-Settlement/FAQs>.

determinations (or even provide “guidance”) is prohibited. Such tools are internal, proprietary, and appear to use guidelines not found in traditional Medicare coverage policies.

Further, MA plans’ use of these contractors often add an impenetrable layer between MA enrollees and providers and the plan itself. As CMS is aware, 42 CFR §422.562(a)(3) states “if the MA organization delegates any of its responsibilities under this subpart to another entity or individual through which the organization provides health care services, the MA organization is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.” In practice, however, when MA plans contract with such care management firms or other such entities, beneficiaries and providers are only able to interact with these delegated contractors; plans often make themselves unavailable and are ultimately unaccountable.

CMS “solicit[s] comment about the specificity of the coverage conditions in Traditional Medicare regulations and whether we should consider, and under what circumstances, allowing MA organizations to have internal coverage criteria in addition to requirements in current regulations.” (p. 79501). **MA plans should not be allowed to have any internal coverage criteria – particularly if it is “proprietary” and unavailable to the public.** We note that 42 CFR § 422.111(b)(7) requires MA plans to disclose “Prior authorization rules and other review requirements that must be met in order to ensure payment for the services.” Undecipherable algorithms that are deemed to be proprietary but are nonetheless used to make coverage decisions for plan enrollees do not meet this requirement.

We appreciate and support CMS’ proposal to refer in §422.101(b)(2) to specific Medicare regulations that including coverage criteria for “Part A inpatient admissions, Skilled Nursing Facility (SNF) care, Home Health Services and Inpatient Rehabilitation Facilities (IRF) as examples of general coverage and benefit conditions in Traditional Medicare that apply to basic benefits in the MA program” (p. 79499). Our experience and independent analysis show that MA plans authorize fewer skilled nursing facility and inpatient rehabilitation facility stays, authorize less home health care³³, and individuals with functional impairments disenroll from MA plans at a higher rate.³⁴

In addition, many MA plans routinely deny admission at inpatient rehab facilities (IRFs) and divert enrollees to lower-acuity care settings, a problem that seems to be exacerbated by plans’ use of the algorithmic support tools discussed above. As recently noted by the president of a care management firm in a letter to our organization, in his firm’s experience acute rehab in IRFs “is not offered for those [enrolled in MA plans] who would appropriately benefit from it, and enrollees are directed to subacute care settings.” In 2017, before the proliferation of such tools, MedPAC found that MA beneficiaries received one third the level of access to IRF care than traditional Medicare beneficiaries.³⁵ **Although not proposed in this rule, we urge CMS to**

³³ *Health Affairs* (May 2020): <https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.00844>

³⁴ Kaiser Family Foundation (KFF) (Sept. 2022):<https://www.kff.org/report-section/beneficiary-experience-affordability-utilization-and-quality-in-medicare-advantage-and-traditional-medicare-a-review-of-the-literature-report/>.

³⁵ Medicare Payment Advisory Commission (MedPAC), Report to The Congress: Medicare Payment Policy 298 (Mar. 2017).

include IRFs, along with comprehensive outpatient rehabilitation facilities (CORFs), and long-term acute care hospitals (LTCHs) in the list of facility-specialty types that are subject to MA network adequacy evaluations per 42 CFR §422.116(b)(2).

When Coverage Criteria is Not Fully Established in Traditional Medicare

CMS proposes that “when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available” (p. 79501). We appreciate that CMS is trying to make MA plan decision-making more transparent, but, in our view, merely requiring MA plans to “provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations” is insufficient (p. 79501).

In addition, plan sponsors are likely to broadly – and inappropriately – interpret what is not “fully” established under Medicare rules to their benefit. If plans wish (and are permitted) to use internal coverage guidelines, they will define as many services as possible as not being “fully” defined. We believe that determining what is and what is not “fully” established will be too subjective, open to interpretation, and could vary widely by plan sponsor.

We see no need for a plan to develop internal coverage criteria, particularly if such criteria is “proprietary” and not publicly available. Requiring disclosure of resources relied upon to develop such criteria, rather than the criteria itself, is inadequate (if CMS’ intent is otherwise, we urge CMS to so clarify in the final rule).

If CMS chooses to continue to allow MA plans to use any internally-generated coverage criteria (whether for basic benefits or when coverage criteria is not “fully” established in traditional Medicare), such criteria must not be allowed to be deemed “proprietary” by a plan, and instead must be made publicly available so beneficiaries and their providers can be adequately informed about and have a meaningful opportunity to challenge a plans’ decision based on such criteria.

Further, if CMS proceeds with its plan not to require MA organizations to provide a pre-determination explanation and opportunity for the public to comment on the MA organization’s coverage criteria, we recommend that instead CMS consider requiring a public comment period for any MA plan coverage criteria to allow for full consideration of the evidence and rationale by patients and providers. A public notice and comment process would shine additional light on the quality of the evidence used to implement more detailed coverage policies by MA plans.

If CMS chooses to continue to allow MA plans to use internally-generated coverage criteria and other utilization management tools, to the extent that CMS does not already routinely review such policies, the agency should explicitly require all plans to submit all utilization management tools and criteria to CMS for review as part of the review of a plan’s annual bid that includes coverage and cost-sharing,³⁶ require the plans to demonstrate why such tools and criteria are

³⁶ See CMS review and approval of MA benefits and associated cost sharing as described at 42 CFR §422.100(f) and prohibition of discrimination against beneficiaries at 42 CFR §422.110.

necessary, and impose enhanced penalties when such criteria is found to be discriminatory either in text or in practice.

MA Plan Use of Step-Therapy for Part B Drugs

We urge CMS to reconsider its decision to continue to allow MA plans to employ step therapy for Part B drugs, as articulated in the proposed rule. Allowing this policy to remain in place creates unnecessary barriers to care for beneficiaries and can lead to harmful consequences. We urge CMS to reinstate the prohibition on MA plans' ability to use step therapy for Part B drugs.

Medical Necessity Determinations

We strongly support CMS' intent to "ensure that MA organizations provide equal access to Part A and Part B benefits as provided in the Traditional Medicare program" (p. 79502). We also strongly support CMS' proposal to limit the discretion of MA plans to deny care, as articulated in the preamble at p. 79502: "When care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the criteria outlined in §422.101(c)(1)(i)." As discussed further below, we urge CMS to include additional requirements concerning deference to treating clinicians.

We also appreciate and support the example that CMS provides: "if an MA patient is being discharged from an acute care hospital and the attending physician orders post-acute care at a SNF because the patient requires skilled nursing care on a daily basis in an institutional setting, the MA organization cannot deny coverage for the SNF care and redirect the patient to home health care services unless the patient does not meet the coverage criteria required for SNF care in §§ 409.30-409.36 and proposed §422.101(b) and (c)."

We also support CMS' proposed application of these plan restrictions as demonstrated by the OIG case examples. We have encountered similar scenarios in which an MA plan's policies included requirements that do not exist elsewhere in Medicare policy, such as the need for additional diagnostic tests before a requested CT scan is approved. Even more common is the scenario in the second OIG case example, wherein an MA plan denied SNF care on the basis that the patient did not have a need for skilled care even though the specific criteria for skilled services under Medicare rules was met. Most egregiously, we not infrequently encounter MA plans that deny SNF care when someone needs services that clearly qualify as skilled nursing services (per se skilled care) outlined at 42 CFR §409.33(b), such as the requisite amount of enteral feeding.

CMS Should Further Articulate Deference to Treating Clinicians and Shared Decision-Making

As noted above, we strongly support CMS' proposal to restrict a plan's ability to deny coverage of care in a particular care setting if it has been ordered or requested by a contracted provider, and the beneficiary in question meets the requisite coverage criteria under Medicare coverage

guidelines. **We urge CMS to more clearly incorporate into these proposals regarding medical necessity determinations, more deference to treating clinicians, and shared decision-making with providers and beneficiaries.**

In addition to CMS' proposal regarding medical necessity referenced above, there are some existing rules concerning provider and beneficiary contribution to plans' decision-making. For example, 42 CFR §422.112(a)(6)(iii) requires plans to establish written standards for "Provider consideration of beneficiary input into the provider's proposed treatment plan." Further, 42 CFR §422.202(b) requires MA plans to "establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures and ensure that the following standards are met: [... including] (3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines." 42 CFR §422.206 further outlines a prohibition on plans' interference with health care professionals' advice to enrollees. As CMS notes in the preamble to this proposed rule, Medicare Managed Care Manual (MMCM), Ch. 4, §10.16 requires every MA plan to make medical necessity determinations based on:

(1) the medical necessity of plan-covered services - including emergency, urgent care and post-stabilization - based on internal policies (including coverage criteria no more restrictive than original Medicare's national and local coverage policies) reviewed and approved by the medical director; (2) where appropriate, involvement of the organization's medical director per 42 CFR §422.562(a)(4); and (3) the enrollee's medical history (e.g., diagnoses, conditions, functional status), **physician recommendations**, and clinical notes [emphasis added].

We support CMS' proposal to codify this existing policy that "MA organizations consider the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes." (p. 79502). **We urge CMS, however, to strengthen this provision regarding MA plan obligations by requiring and then following – not considering – the input of a treating physician or other clinicians. Further, MA plans should be required to offer some deference to, or shared decision-making with, treating providers.** In addition, treating clinicians should be allowed to access the entirety of an individual patient's medical records as a whole in order to make as informed treatment decisions as possible. This requirement should apply across services and care settings. As discussed below, CMS seems to touch on this through the proposed definition of "course of treatment" at §422.112, but more specificity is needed.

Our experience serving Medicare beneficiaries, reinforced by numerous interactions with providers such as SNFs, home health agencies and physicians, shows that MA plans all too often substitute their own clinical judgment for that of the treating physician or other clinician, often without even evaluating the beneficiary in person.

Providers often describe the plan-provider relationship to us as being "one-sided" with little or no participation of providers' views. The treating provider's judgment from the patient's bedside is second to the plan's. Neither the providers' nor the patients' and their families' needs and wishes are accounted for. One physician specializing in home care with whom we recently spoke commented: "I want the plan to ask my approval before terminating services [but that doesn't

happen]; the plan needs to get my input. There needs to be some balance of shared decision-making.”

In some care settings, such as SNFs and home health, there is often an initial decision that someone needs medically necessary care in a requisite care setting, but the care plan needs to be developed over a number of days or visits as the care team assesses the individual’s needs. For example, a hospitalist or discharging physician will write an original plan, which the MA plan may follow or adapt. Often, if an MA plan authorizes coverage, instead of consulting with the treating clinicians, a set number of days or visits is determined at the outset with little flexibility on the part of the plan and little opportunity for providers to revise the care plan as needed. The primary care team should have the ability to adjust and revise the orders, based upon their determination of the patient’s needs and acclimation to the SNF, home, etc. There should be shared decision-making among clinical staff and the MA plan – the plan should give significant deference to the treating clinicians, and should be required to make good faith, reasonable efforts to reach and work with the provider in order to solicit and incorporate such input.

Appropriate Use of Prior Authorization

We strongly support CMS’ proposal to codify at a new §422.138(a) that “Appropriate prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care” (p. 79503). This proposal, along with the proposal codifying that MA plans cannot use coverage guidelines more restrictive than those in traditional Medicare, should provide significant, additional protection to MA enrollees. We also note that in order to further enhance consumer protections, CMS should, as discussed above, both explicitly require MA plans to provide deference to treating physicians who prescribe/order care, and enhance requirements for MA denial notices so that when requests are denied, plans have to clearly articulate their finding of facts, rationale, and criteria applied so that beneficiaries and providers can meaningfully challenge erroneous or inappropriate plan decisions.

We support the codification of section 10.16 of Chapter 4 of the MMCM which currently states that if the plan approved the furnishing of a service through an advance determination of coverage, it may not deny coverage later on the basis of a lack of medical necessity.

We applaud CMS for reminding plans in the preamble:

that section 1852(b) of the Act states that an MA plan may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status–related factor described in section 2702(a)(1) of the Public Health Service Act. Additionally, per CMS regulations at § 422.100(f)(2), plan benefit designs may not discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. We consider prior authorization policies to be part of the plan benefit design, and therefore cannot be used to discriminate or direct enrollees away from certain types of services (p. 79503-4).

As noted above, to the extent that CMS will still allow plans to craft their own utilization management criteria, including prior authorization, the agency should explicitly require all plans to submit all utilization management tools and criteria to CMS for review as part of the review of a plan's annual bid that includes coverage and cost-sharing, and impose enhanced penalties when such criteria is found to be discriminatory either in text or in practice.

When noting the agency's inability to provide an estimate of the impact of this provision, CMS notes in the preamble that it cannot do so "because we require detailed knowledge of proprietary plan information on the frequency and specific services for which prior authorization is done in each plan" (p. 79504). This is precisely the information that should not only be required to be reported to CMS, but should also be made publicly available. As noted above, among stronger enforcement measures, we urge CMS to expand plan reporting requirements in order to give both the agency and beneficiaries a more accurate picture of how individual MA plans operate. Such information should not be allowed to be proprietary.

Continuity of Care

We appreciate that CMS acknowledges and reflects stakeholder feedback in the preamble:

that MA coordinated care plans' prior authorization processes sometimes require enrollees to interrupt ongoing treatment. We also have received complaints that MA plans require repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care or are receiving ongoing treatments for a chronic condition. When MA plans require repetitive prior approvals, enrollees may face delays in receiving medically necessary care or experience gaps in care delivery that threaten an enrollee's health (p. 79504).

We are one of those stakeholders, and we confirm that such inappropriate and harmful plan behavior regularly impacts both beneficiaries and providers with whom we speak. Thus, we strongly support CMS' proposal that MA "prior authorization policies must reflect that all approved prior authorizations must be valid for the duration of the entire approved prescribed or ordered course of treatment or service" (p. 79504). CMS provides a couple of examples: "if an MA coordinated care plan has approved a prescribed or ordered course of treatment or service for which the duration is 90 days, then the MA coordinated care plan's prior authorization approval must apply to the full 90 days, and the MA coordinated care plan may not subject this treatment or service to additional prior authorization requirements prior to the completion of the approved 90-day treatment or service"; in addition, "if the MA coordinated care plan approves a prescribed or ordered course of treatment for a series of five sessions with a physical therapist, the MA coordinated care plan may not subject this active course of treatment or service to additional prior authorization requirements" (p. 79504).

This provision will undoubtedly help curb some premature termination of services by MA plans. CMS must take measures, however, to ensure that this provision will not lead to even greater stinting of care on the front end. For example, if a plan knows that it will be bound by its own decision concerning approved care, it may be incentivized to authorize less care at the outset than it otherwise would have (for example, a treating clinician might determine that a patient needs 4 weeks in a SNF but the plan only authorizes 2). This dynamic makes input and direction from the treating clinician all the more important in order to ensure that the initial authorization of coverage is adequate. CMS seems to acknowledge and address this in the manner it defines

“course of treatment”, discussed below. Further, there is a likelihood that whatever care a plan authorizes – and under this provision would be bound to provide – will serve as a hard and fast end date of coverage, with even less regard than usual to whether the individual actually needs additional care beyond the pre-determined end date.

We recognize that MA plan sponsors will likely vigorously oppose this provision. We also recognize that in some cases, individuals meet their treatment targets or goals sooner than initially projected (although in our experience it is more common that someone needs additional care than originally anticipated). We believe that it is reasonable to allow some flexibility to initial coverage decisions based on a demonstrable change in condition; however, this must work “both ways.” In other words, a plan – in consultation with and agreement by treating providers and the beneficiary – should be allowed to demonstrate that under Medicare coverage guidelines treatment goals were met sooner than originally anticipated. Conversely, if an individual needs care beyond the period of time or number of visits originally anticipated, deference should be given to the treating providers and in turn plans should have the burden to demonstrate why additional care is not necessary. In addition, as discussed further below, CMS should consider mandating a minimum period of time that an MA plan denial subsequently reversed on appeal remains in effect and not subject to another denial.

CMS proposes to define “course of treatment” at §422.112 “as a prescribed order or ordered course of treatment for a specific individual with a specific condition, as outlined and decided upon ahead of time, with the patient and provider. (A course of treatment may, but is not required to be part of a treatment plan).” CMS also proposes to define an “active course of treatment” “as a course of treatment in which a patient is actively seeing a provider and following the prescribed or ordered course of treatment as outlined by the provider for a particular medical condition” (p. 79504).

We strongly support this definition of “course of treatment” including the manner in which it applies to the duration of approved prior authorization requests. As defined, this approach places the prescribing and/or treating clinician at the forefront and in control of their patients’ care, with an MA plan playing an appropriately subsidiary role, including confirming the individual’s diagnosis and medical necessity of the treatment or care in question. We could not agree more with this approach to care and hierarchy of decision-making. This is the way that care should be, even in a managed care plan. But we cannot emphasize enough how, in practice, in our experience MA plans operate from the completely opposite perspective, in which plans dictate and control all care. As noted above, providers describe to us how “one-sided” decision-making and communications currently are between plans on the one side and providers and their patients on the other. While the approach CMS outlines here is both rational and just, effectuating these proposals may be a significant change in course for plans that will require aggressive oversight, enforcement and education. If it is truly CMS’ intent to have providers drive the care of MA enrollees – rather than plan utilization management employees – CMS must be extremely explicit and firm about this. With current rampant MA plan use of prior authorization, proprietary algorithmic tools that supplant clinician decision-making, and blanket denials that provide conclusory and inadequate justification, CMS’ proposed revisions – if enforced – would represent a dramatic and welcome sea change for MA enrollees’ access to care.

We also support CMS’ proposal that MA plans have “as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day

transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider” (p. 79504). This includes enrollees who are new to a given MA plan. This provision will help ensure that beneficiaries do not need to immediately go through the burden of obtaining approval, including requisite diagnostics, in order to maintain continuity of care. We further urge CMS to give deference to the treatment decisions of providers who have given care to (and previous insurers who have covered) the beneficiaries services during a course of treatment.

We appreciate that CMS reminds MA plan sponsors that under the Medicare statute the agency “is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits” (p. 79505). Importantly, if CMS finds that plan sponsors are unable or unwilling to follow these proposals that if enacted and enforced will considerably strengthen consumer protections, the agency can decline to contract with plan sponsors. Insurance companies do not have an evergreen right to participate in and profit from the Medicare program.

Utilization Management (UM) Committees

To the extent that CMS continues to allow MA plans to develop their own utilization management criteria, we support CMS’ proposal to require MA organizations to establish a Utilization Management Committee. As noted above, any UM policies should not be allowed to be deemed proprietary by the plan, and must be publicly available. Further, if CMS does not already review each plan’s UM policies during the bid review process, we urge the agency to do so.

We generally support CMS proposals concerning the duties of UM committees and urge CMS to require such entities to review, and determine the necessity of, all internal coverage criteria used by the MA plan as proposed. Such committees should also be required to engage in internal oversight of plan operations, including randomized audits, assessment of rates of and reasons for denial, and duration of time between denials issued, and should be required to report such findings to CMS. With respect to membership, such committees should include individuals who are familiar with Medicare coverage rules (in addition to clinicians).

Additional Areas for Consideration and Comment

Termination of Services in Post-Acute Care

We appreciate that CMS articulates in the preamble complaints it has received “about potential quality of care issues regarding early termination of services in post-acute care settings by MA organizations.” Such complaints:

allege that MA organizations are increasingly terminating beneficiaries’ coverage of post-acute care before the beneficiaries are healthy enough to return home. It is further alleged that, in some situations, even after a beneficiary has successfully appealed to the Quality Improvement Organization (QIO) and received a favorable decision to reauthorize coverage of services delivered by providers of services described in §§ 422.624 and 422.626, the MA organization sends another notice of termination of services a day or two after the coverage was reinstated (p. 79507).

We acknowledge that we are one source of such complaints, and that such behavior by MA plans persists. As noted in the proposed rule, the provisions that restrict MA plan’s ability to deny coverage of services or care in a particular setting when a contracted provider has made the order or request will help address this scenario, as will the provisions that define “course of treatment” driven by providers. As noted above, this will require aggressive oversight and enforcement of these provisions.

CMS solicits comments on potential changes to existing rules or potential new rules concerning “termination of services from home health agencies, SNFs, and comprehensive outpatient rehabilitation facilities and how enrollees must be notified of upcoming terminations of services” and how to “better manage incentives between MA organizations and post-acute care providers to deliver the best possible care for Medicare beneficiaries” (p. 79507). CMS offers some topics for comment, including:

- “How MA organizations preauthorize treatment in discrete increments and the extent to which our proposals (at proposed §§ 422.101(b) and (c) and 422.112(b)(8)) may address or limit these practices”

In our experience, MA plans do indeed often only authorize coverage or care in “discrete increments.” For example, we were recently told by a SNF that one MA plan they contract with only authorizes SNF coverage “4 days at a time.” Similarly, a provider association informed us that sometimes MA plans will only authorize home health services “one visit at a time.” We believe that CMS’ proposals in this rule will help this situation, including those defining “course of treatment”, but as discussed above this will require CMS to even more explicitly instruct plans that contracted providers must drive treatment decisions rather than plans.

- “Whether enrollees should have additional time to file appeals or be able to file late appeals to the QIO regarding terminations of services”

We strongly support providing enrollees with additional time to file appeals, including late appeals, to the QIO regarding termination of services. At a time when an individual is going through considerable care needs, plans do not often adequately inform either beneficiaries or their providers about the reasons for termination of services, often leaving beneficiaries in the dark and scrambling to mount a challenge. Giving beneficiaries more time to appeal, coupled with stronger written notice requirements and greater deference to the treating clinicians, will help.

- “Whether enrollees should receive information from the MA plan regarding the basis for termination of services (for example, the clinical rationale for termination of services) as part of the termination notice and without the enrollee having to request an appeal to the QIO (see §422.626(e)(1) and (2));”

As discussed in the introductory/overview comments to this section of the proposed rule, such a requirement already exists in Medicare rules, but is neither routinely followed nor enforced. We urge CMS to require MA plans, as a default for all coverage denials and terminations, to provide detailed written information about their coverage decisions in a manner that makes it clear what information is required, and what might be missing (see, e.g., Detailed Explanation of Non-

Coverage). A beneficiary should not be required to file an appeal in order to receive an adequate explanation of why coverage is denied or terminated.

- “When coverage is reinstated based on a QIO decision, whether the enrollee should have more than the 2 day period from the date of a new termination of services notice before coverage can be terminated again by the MA organization, taking into account any medical necessity determinations made by the QIO.”

We have provided assistance to numerous MA enrollees who encounter this very situation – a new MA termination notice within a day or several days of receiving a favorable decision from the QIO reversing an MA plans’ termination of services. For example, a *CMA Alert* we posted in April 2022 outlined the experiences of one of our clients, an 80-year old woman enrolled in United Healthcare who had to file more than 10 appeals on UnitedHealthcare’s (through their contractor naviHealth) repeated decisions to terminate her coverage of a SNF stay as she tried to regain mobility after a hip operation.³⁷ Similar to CMS’ proposals to require continuity of care during a course of treatment, including during transition periods, CMS should impose a minimum time period during which MA plans cannot issue a termination notice after their prior termination decision has been reversed by the QIO. The MA plan should have to meet a higher burden of proof demonstrating a significant change in condition or need – particularly if the provider disagrees with the termination. CMS should consider a grace period of 14 days, at minimum, before a plan can issue another termination notice. This time period would allow a reasonable amount of time to reassess a beneficiary’s condition.

F. Request for Comment on the Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS seeks comment on whether CMS should revise its MA R&I program regulation to include parameters for permissible gift cards being offered as MA reward items. We oppose allowing any reward items to lure people into specific MA plans who otherwise would be better suited to traditional Medicare or to another MA plan. In addition, the use of gift cards and other inducements can function to cherry pick enrollees if they are targeted, for example, at potential enrollees that fit certain demographics that would find specific inducements more appealing. CMS should significantly curtail the use of such R&I inducements.

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

CMS proposes to require section 1876 cost plans to cover the COVID-19 vaccine and its administration without cost-sharing. We support this requirement.

³⁷ *CMA Alert*, “When Artificial Intelligence in Medicare Advantage Impedes Access to Care: A Case Study” (April 21, 2022), available at: <https://medicareadvocacy.org/ai-plus-ma-equals-bad-care-decisions/>.

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

CMS proposes to update the agency’s existing reviewer standards to require that the physician or other health care professional conducting the review must have expertise in the field of medicine that is appropriate for the item or service being requested before a plan can issue an adverse decision. We strongly support this proposal and urge CMS to strengthen it further.

In the context of rehabilitative medicine, often, a rehabilitative medicine physician recommends clinically appropriate care for an MA patient, but that care is denied for lack of medical necessity because the medical director (or more commonly, the non-physician staff of the MA plan) reviewing the request is not trained in rehabilitative medicine. It is a significant burden on rehabilitation providers to educate and explain clinical care within their specialty to an MA organization medical director (or non-physician staff) when those decision-makers do not have the experience or training to adequately understand the medical necessity of the care being prescribed. It is essential that the medical directors (and their non-physician clinical staff) of the MA plan are appropriately trained in directly related specialties to determine medical necessity.

We note that this proposal does not require the reviewing provider to be of the same specialty or subspecialty as the treating physician, and that plans would have discretion to determine on a case-by-case basis what constitutes “appropriate expertise” based on the relevant circumstances. We understand that reviewers may have some expertise in a field without a specialty or subspecialty certification. However, we urge CMS to add more specific guardrails to ensure that appropriately qualified reviewers are involved in decision-making around coverage for particularly complex services, including post-acute care.

For example, CMS already details requirements for inpatient rehabilitation facilities (IRFs) to be led by a rehabilitation physician, the definition of which does not specify a particular certification. Instead, the regulations require rehabilitation physicians to have specialized training and experience in IRF care. We believe a similar requirement should be applied to MA plans when reviewing the appropriateness of an admission to an IRF or prescription of other rehabilitation services. When a plan is seeking to override the clinical judgement of a rehabilitation physician with specialized training and experience in rehabilitation who has prescribed a particular item or service for an individual in need of post-acute care, this determination should be made only by a similarly qualified physician representing the plan. MA plans should provide deference to these physicians unless there is evidence in the patient record that specifically contradicts the physician’s medical necessity determination.

K. Call Center Interpreter Standards (§§ 422.111(h)(1)(iii)(A) and 423.128(d)(1)(iii)(A))

CMS proposes to require MA organizations and Part D sponsors to use interpreters that adhere to generally accepted interpreter ethics principles, including confidentiality; demonstrate proficiency in speaking and understanding at least spoken English and the spoken language in

need of interpretation; and interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology. We support this proposal.

More than 6.5 million older adults have Low English Proficiency (LEP). Given its complexity, health care information can only be communicated effectively in an individual's primary language, and most people's health care needs increase and become more complicated as they age. Setting standards for call center interpreters is critical to ensuring access to care for older LEP enrollees.

M. Part C and Part D Midyear Benefit Changes and Part D Incorrect Collections of Premiums and Cost Sharing (§§ 422.254, 423.265, 423.293, 423.294)

CMS proposes to clarify that any changes to non-prescription drug benefits, cost sharing, and premiums are prohibited starting after plans are permitted to begin marketing prospective contract year offerings on October 1 of each year for the following contract year (consistent with § 422.2263(a)) and through the end of the applicable contract year. We support this clarification.

CMS further proposes to codify a requirement that once a Part D sponsor is permitted to market prospective plan year offerings for the following contract year it must provide the benefits described in its CMS-approved plan benefit package for the contract year without modification, except where a modification in benefits is required by law. We support this codification.

O. Updating Translation Standards for Required Materials and Content (§§ 422.2267 and 423.2267)

We support the proposal to require plans to provide translated and accessible materials and auxiliary aids and services to enrollees on a standing basis rather than requiring repeated requests by plan members. We also support specifically applying these requirements to individualized plans of care for Dual Eligible Special Needs Plans (D-SNPs).

We further recommend that CMS adopt and apply these rules to itself, i.e., establish procedures that allow Limited English Proficiency (LEP) Medicare enrollees to establish with CMS a standing order for CMS to provide translated correspondence and publications (e.g., the annual *Medicare & You*).

In addition, we urge CMS to extend the standing order rule to interpreter services. If an LEP plan enrollee has requested an interpreter for live, real-time communication, e.g., over the phone or in connection with a visit to an in-network provider, the enrollee should have the option to establish a standing order for interpretation. Plans should implement the request for both incoming and outgoing calls to the enrollee and should proactively ensure that interpreters are arranged for in-network appointments. Plans should be required to note in the enrollee's record the need for interpretation and the specific language needed. The same rule should apply to CMS itself. When requested by any LEP enrollee, CMS should as a matter of course note in the

enrollee’s Medicare record a standing order for interpretation and the language required, to be used for both incoming and outgoing calls.

Finally, we take this opportunity to restate the longstanding request of many advocates for the agency to revisit its threshold requirements for translations by MA and Part D plans. Current 42 C.F.R. § 422.2267(a)(2) and its companion regulation for Part D, 42 C.F.R. § 423.2267(a)(2), require translation of certain marketing and communications materials “into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.” We recommend setting a more inclusive threshold that, in addition to using percentage of individuals in a PBP, also requires translation if a numerical threshold is reached. That threshold could be based either on the number of individuals speaking the non-English language in the PBP or the number enrolled in the plan.

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

Overarching Comments

As the Center noted in our comments to CMS’ Request for Information about Medicare Advantage,³⁸ when deciding how they want to access their Medicare coverage, Medicare beneficiaries face myriad, complicated choices among unequal options. These choices include disparate enrollment rights and opportunities between Medicare Advantage and Medigap plans (for example, while people can get in and out of an MA plan on an annual basis, most people have limited opportunities to purchase a Medigap plan – a fact many people discover too late).

As noted in a 2022 Commonwealth Fund blog³⁹ exploring Medicare Advantage plans and choice, health economists and Medicare experts “said choosing among plans can be difficult, even for the savviest consumers” and such experts “agreed that most beneficiaries aren’t making informed or active decisions. Instead, many choose plans based on advertising, word-of-mouth, or brand loyalty, then stay with those plans year after year, even if another plan would better serve their interests.”

Unfortunately, misconduct surrounding the sale of Medicare products, in particular Medicare Advantage (MA) plans, abounds. Last year, CMS reported that Medicare beneficiary complaints about Medicare Advantage (MA) marketing more than doubled between 2020 and 2021. On November 3, 2022, the Senate Finance Committee Majority Staff issued a report titled “Deceptive Marketing Practices Flourish in Medicare Advantage”⁴⁰ stating that it “found evidence that beneficiaries are being inundated with aggressive marketing tactics as well as false and misleading information.”

³⁸ CMA Comments to CMS’ RFI re: MA (August 31, 2022), available at: <https://medicareadvocacy.org/wp-content/uploads/2022/09/MA-RFI-Comments-2022.pdf>

³⁹ Commonwealth Fund, “Taking Stock Of Medicare Advantage: Choice” (March 2022), available at: <https://www.commonwealthfund.org/blog/2022/taking-stock-medicare-advantage-choice?emci=4f2a4714-2622-ed11-bd6e-281878b83d8a&emdi=ea000000-0000-0000-0000-000000000001&ceid=%7b%7bContactsEmailID%7d%7d>.

⁴⁰ Senate Finance Committee, [Deceptive Marketing Practices Flourish in Medicare Advantage](#) (November 2022)

We applaud CMS for responding to this increased misconduct by proposing the additional consumer protections outlined in this proposed rule. We support each and every proposal CMS offers concerning marketing, but in some places urge CMS to go further to adequately protect Medicare beneficiaries.

As the Center has asserted elsewhere,⁴¹ financial incentives on the part of MA plans and those who sell them play a prominent role in fueling this misconduct. There are significant profits that insurance companies make on the MA program, and also significant commissions to be earned by agents and brokers (set, in part, by Medicare program itself). While MA payment (and overpayment) is beyond the scope of these provisions, and we know that CMS is making efforts to make MA plans more accountable through RADV audits and revised payment methodologies, one missing element with respect to marketing is the disparate commissions to paid to agents and brokers for MA plans vs. Part D plans. As we noted in a November 2022 CMA Alert, for 2022, CMS set the maximum national commission for initial enrollment in MA plans at \$573 per beneficiary (in most parts of the country), whereas the maximum national commission for first-time Part D plan enrollment, for those in traditional Medicare was \$87. This wildly disparate payment structure helps drive those seeking commissions to push people towards MA plans, even if that is not the best option for them. As we suggested in our above-referenced comments to CMS' RFI, we urge CMS to overhaul the agent/broker compensation structure, including requiring agents and brokers to disclose commissions they receive for the sale of a given product so that individuals have a better understanding of incentives behind sales pitches.

We also urge CMS to revisit its distinction between marketing and communications and their respective, corresponding requirements. As we have indicated in prior comments to CMS,⁴² we disagree with the agency's assertion that documents which may impact an enrollment decision, but are not intended to do so, don't qualify as marketing documents. If a beneficiary uses a plan-issued document to make enrollment choices, the sponsor's intent is irrelevant. Plan- and agent/broker-issued content should be subject to stringent oversight by CMS to ensure accuracy and readability.

We reiterate concerns about MA plans' marketing of supplemental benefits, particularly SSBCI that might not be available to everyone in a given plan. We have heard from SHIP programs that in some areas, the top issue that drove people to seek SHIP counseling during the last annual enrollment period were plan-issued debit cards, or flex card benefits – people demanded to be enrolled in the plan that offered the most money, without regard to any other considerations. One example provided by a SHIP counselor concerned a client who was convinced to look at issues in addition to debit card she wanted, and discovered that none of the five providers she was currently seeing were in network of the plan that offered the highest value debit card she sought. At the beginning of the year, the same SHIP programs report that one of the top issues they have heard about concern how such debit or flex cards don't, in fact, work as the beneficiary was led to believe by the plan or agent/broker.

⁴¹ See, e.g., *CMA Alert "Senate Report Highlights Widespread Medicare Advantage Marketing Misconduct – But the Driving Forces of Misconduct Are Broader"* (Nov. 10, 2022), available here: <https://medicareadvocacy.org/ma-misconduct/>.

⁴² See, e.g., *CMA Comments to Proposed CY 2021 and 2022 Part C&D rule* (April 2020), available at: <https://www.medicareadvocacy.org/wp-content/uploads/2020/04/CMA-CD-Comments-2020.pdf>.

Further, we urge tighter oversight of and restrictions concerning marketing by health care providers and in a health care setting (for example, we encounter Medicare beneficiaries who are marketed to in their hospital beds, and provider group presentations and communications that skirt requirements or cross lines).

We urge CMS to consider prohibiting MA plans from providing additional compensation to agents and brokers to complete health risk assessments, which further incentivizes agents and brokers to sell MA over other products. As discussed further below, we urge CMS to prohibit the sale of ancillary health products along with MA plans.

It is not our intent to paint all agents and brokers with one brush – we know there are, quite literally – honest brokers. But the financial incentives inherent in the current Medicare marketplace are such that too many place their own pecuniary or financial interests above the needs of beneficiaries, leading to many of the problems CMS identifies in this proposed rule. In finalizing these proposals, as well as drafting any additional rules, CMS should not factor in the pecuniary or other business interests of agents, brokers, TPMOs, marketing firms or other entities that are involved in the selling of Medicare products. Rather, consumer protection should be paramount.

Comments to Specific Proposals

We strongly support all of CMS’ proposed changes concerning Medicare Advantage and Part D marketing. While we believe that some provisions can be strengthened further, and there are issues that remain unaddressed that could further protect consumers – as discussed below – we applaud CMS for responding to marketing misconduct in the manner it has done through this proposed rule.

We agree with CMS that “the changes proposed in this regulation strengthen CMS’ ability to ensure MA and Part D marketing to beneficiaries is not misleading, inaccurate, or confusing” (79524). We offer our comments to specific proposals below, in order of their discussion in the preamble:

- Submission of marketing materials by TPMOs

CMS is proposing to require third party marketing organizations (TPMOs) to submit their marketing materials developed for multiple MA organizations and Part D sponsors (and their specific plans) to CMS through HPMS, and only after receiving prior approval of each of the plan sponsors on whose behalf the materials were developed. We support this proposal that would subject such materials to CMS review.

- Prohibition of ads that market MA plans with confusing words, imagery, logos

We share CMS’ concern that, as a result of misleading advertisements, an increasing number of beneficiaries are being misled into believing the entity they are contacting (or have been contacted by) is Medicare or the Federal Government. We, too, have encountered “beneficiaries who mistakenly believed they were calling Medicare rather than a private MA or Part D plan or its agent or broker” due to receiving a flyer or other inducement (p. 79525).

We support CMS' proposal to specifically prohibit the misleading use of the Medicare name, CMS logo, and products or information issued by the Federal government (including the Medicare card). Particularly egregious examples that the Center has found include: <https://www.medicareplanfinder.com/> (which, of course, is impersonating the official Medicare Plan Finder at <https://www.medicare.gov/>), and <https://medicare.com/> ("powered by eHealth" which seems to try to capture traffic to the official medicare.gov site).

We urge CMS to provide further examples of prohibited deceptive advertising to include materials that are designed to look like it is coming from another "legitimate" source, such as a provider. For example, in the Fall of 2022, one of our own Medicare-eligible staff at the Center for Medicare Advocacy received emails designed to appear as if they were health updates sent from her physician's office from a "Follow My Health" platform, imploring her to sign-in to her account to view a secure message. When opened, it was an advertisement for MA plans – the message prompts one to "Review your 2023 Medicare Advantage choices".

We appreciate that CMS reiterates that if it determines that such information has been used in a misleading manner by a first tier, downstream or related entity, CMS will address the issue with the sponsoring MA or Part D plan, and hold the sponsoring organization accountable. We urge CMS to go further and articulate plan sponsors' obligation to actively screen and monitor those that sell their products, including review of websites, brokerage firm names, etc., to ensure that misleading information is not allowed to propagate unless and until CMS might find it. Plans know to whom they pay commissions; they should be required to adequately screen these parties. Such efforts should be part of CMS' proposed requirement that plan sponsors develop oversight plans to monitor agent/broker activities, discussed elsewhere in this rule.

- Further restrict the use of superlatives by prohibiting all superlatives unless substantiating supporting data is also provided with the material

We support CMS' proposal that would prohibit all superlatives, including those used in logos and taglines, unless substantiating supporting data is also provided with the material. We further support CMS' requirement that the supportive documentation or data must reflect data, reports, studies, or other documentation to have been published either in the existing contract year or the prior contract year.

- Prohibiting marketing of benefits in a service area where those benefits are not available

We support CMS' codification of previous guidance "providing that marketing activities should be limited to a plan's service area unless doing so was unavoidable, such as advertising in a local newspaper that may be distributed outside a service area. In cases where marketing outside a service area was unavoidable, CMS's guidance provided that the plan's service area be disclosed" (p. 79526). We appreciate that CMS specifically calls out the significant increase in national marketing which promotes benefits that might not be available in all service areas or to all Medicare beneficiaries in the amounts often advertised. We agree with CMS that the examples it provides, including Part B premiums reductions, dental benefits with high coverage amounts, and other similar offerings in these commercials:

ha[ve] the effect of getting beneficiaries to contact the company [but] is a misleading tactic that is more likely designed to attract a beneficiary's attention so that the beneficiary will call the number and then, be subject to additional marketing and potentially switched to a plan not that is not well suited to meet the beneficiary's health care needs" (p. 79526-7).

We urge CMS to further scrutinize the exception to this proposal when "unavoidable." For example, if there is a substantial likelihood that an ad that might be accurate in one area is broadcast in another area(s) where it is inaccurate, CMS should err on the side of prohibiting such advertisement. Television advertisements in the Washington DC, area, for example, are often also broadcast throughout local jurisdictions in Maryland and Virginia, where plan offerings can vary considerably.

- Prohibition of ads that don't mention a specific plan by name

We support CMS' proposal to prohibit marketing unless the names of the MA organizations or Part D sponsors that offer the benefits are being advertised are clearly identified. CMS highlights how ads that mention additional benefits, zero premiums, or other enticements don't identify specific products and often serve as a lead generator to obtain beneficiary contact information. We also support the rationale for CMS making this proposal, including giving more agency to individual beneficiaries concerning information they are seeking. We also support CMS' various proposals concerning print, television, radio, online, or social media-based advertisements, including that advertisements must have MA organization, Part D sponsor, or marketing names in 12-point font and may not be solely in the disclaimer or fine print.

- Prohibiting marketing based on information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, costs that dually eligible beneficiaries are not responsible to pay, or other unrealized costs of a Medicare beneficiary

We support CMS' proposal to limit such marketing based on the rationale that beneficiaries are not saving the advertised amount of money because they would never have incurred many of those out-of-pocket expenses. We urge CMS to also prohibit advertising of the existence of generic out-of-pocket caps on costs, since all MA plans are required to have a Maximum Out-of-Pocket Limit (MOOP). Similarly, when the Part D out-of-pocket cap pursuant to the Inflation Reduction Act is implemented, Part D and MA-PD plans be similarly restrained.

- Clarifying that the prohibition on door-to door contact without a prior appointment still applies after collection of a Business Reply Card (BRC) or Scope of Appointment (SOA)

We strongly support CMS' proposal to clarify that contacting a beneficiary at his or her home is considered to be door-to-door solicitation unless an appointment at the beneficiary's home at the applicable date and time was previously scheduled. People are often most susceptible to high pressure sales tactics in their own home and CMS must make every effort to limit unwanted agent/broker visits without explicit consent from the beneficiary.

As referenced in the introduction to our comments to the marketing provisions in this rule, we urge CMS to take additional steps concerning the SOA form, and, in turn, what agents and brokers can discuss with Medicare beneficiaries during sales visits. Under current Medicare marketing rules, MA organizations may not “Market non-health care related products to prospective enrollees during any MA sales activity or presentation. This is considered cross-selling and is prohibited.” 42 CFR §422.2263(b)(4). We urge CMS to expand the prohibition on cross-selling to include health care related products. As the Center recently highlighted in a November 2022 report,⁴³ many of the same people selling Medicare Advantage products both highlight and rely upon MA products’ shortcomings in order to promote the sale of ancillary health products, including extra dental, hearing and vision policies. Current rules allow a broad range of exploitative behavior, including the sale of ancillary health products during MA sales. An update to this rule is sorely needed.

- Requirement that plans notify individuals of the ability to opt out of phone calls regarding MA and Part D plan business

CMS currently requires that MA organization and Part D sponsors provide beneficiaries an opportunity to opt out of being contacted concerning plan business via a one-time notice. CMS proposes to require each MA organization and Part D sponsor to provide the opt-out information to all its enrollees, regardless of plan intention to contact, at least annually in writing, instead of just one time. While we support CMS’ intent to require more opportunities for members to opt out of being contacted, we urge CMS to better protect beneficiaries’ interests (rather than plan sponsors’ interests) by prohibiting plans from engaging in unsolicited contact with plan enrollees. We often hear about individuals enrolled in a stand-alone Part D plan being contacted by the plan sponsor in an attempt to get the individual to switch to one of the sponsor’s Medicare Advantage products. This is not a solicited contact, rather it is a cold call, and has nothing to do with the provision of care or benefits of an individuals’ current coverage, and therefore should be prohibited. In other words, CMS should prohibit plan sponsors from calling current members to discuss Medicare products. At the very least, members should be able to opt-in to receiving such contact rather than having to actively opt out under current rules (even if they are notified at least annually under CMS’ proposal).

If CMS chooses not to follow this suggestion, and instead proceeds with its proposed change, we urge CMS to make sure that the format of the opt out option is prominent, explicit (otherwise it is likely to be buried in other plan materials) and as easy as possible for a member to follow up with – e.g., able to be exercised by a phone call to the plan call center (rather than a written response to the plan). Further, each time a plan sponsor makes such a contact to a member, a disclaimer should be provided – whether via phone call, email or mail – that a person can opt out of further contact at any time.

⁴³ *Center for Medicare Advocacy Alert, “Sale of “Ancillary Products” to Fill Gaps in Medicare Advantage Highlight Both Coverage Shortfalls and Need for Stronger Regulation of the MA Marketplace”* (Nov. 17, 2022), available here: <https://medicareadvocacy.org/ma-and-selling-extra-products/>.

- Prohibition on sales presentations that immediately follow an educational event

As noted in the preamble, due to revisions to marketing guidelines in recent years, codified in the January 2021 final rule, “CMS currently permits MA organizations and Part D sponsors participating in educational events to set up future personal marketing appointments and to collect beneficiary contact information including Scope of Appointment forms (SOAs) at educational events. Our regulations also permit marketing events to immediately follow an educational event, provided the beneficiary is made aware of the change and is given an opportunity to leave prior to the beginning of the marketing event” (p. 79529).

CMS states that since the 2021 final rule, “complaints to CMS have increased alleging unsolicited contact. We believe that some of these complaints may be attributed to the collection (and later use) of contact information or SOA cards at educational events” (p. 79529). CMS also notes that it has heard from beneficiary groups requesting that CMS reinstitute the beneficiary protections from the MCMG that were not included in the January 2021 final rule regarding educational events. The Center for Medicare Advocacy acknowledges that we are one of those beneficiary groups and have been pushing for such reinstatement ever since the consumer protections were removed.⁴⁴

As we have repeatedly asserted to CMS, these changes appear to directly conflict with both the plain text and intent of Section 103 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which prohibits “Sales and marketing activities for the enrollment of individuals in Medicare Advantage [and Part D plans] plans that are conducted” at educational events. As we stated in our comments to the proposed CY 2021 and 2022 rule:

The distinction between educational and marketing events was created, in part, so that beneficiaries would not be pressured to enroll in an MA or Part D plan during an educational event. While the distant time and location requirements separating these two types of events might inconvenience an agent/broker who wishes to sell a product to a prospect who appears interested immediately following an educational event, this changes the tenor and dynamic of educational events. Presumably individuals show up for educational events because they are advertised as such; if they were interested in engaging in a possible sale they have opportunities to do so, whether it is through an advertised marketing session, through an individual agent/broker, or directly through a plan. If agents/brokers can immediately make a sale after an educational event, it turns such events that were designed to be without pressure into a hunting opportunity for agents/brokers or plan representatives. The previous requirements mandating that any marketing events occur distant in both time and place allowed a cooling off period for beneficiaries between an event where they came to learn and one in which they are being pressured to buy something.

We are grateful to CMS for reversing course and reinstating these important consumer protections that reimpose a barrier between educational and sales events. We could not agree

⁴⁴ See, e.g., CMA Comments to Proposed CY 2021 and 2022 Part C&D rule (April 2020), available at: <https://www.medicareadvocacy.org/wp-content/uploads/2020/04/CMA-CD-Comments-2020.pdf>.

more with CMS' statement that "We believe the beneficiary needs to be in charge of and control whether they want to be contacted, by whom, and in what form" (p. 79529).

Accordingly, we strongly support CMS' proposal to reinstate the prohibition on accepting Scope of Appointment (SOA) cards or the collection of beneficiary contact information at educational events, since such events are "meant to provide generic information about the different options, rather than to persuade beneficiaries to enroll in any type of plan (for example, MA-PD or Medigap) or in a plan offered by any specific sponsoring organization" (p. 79529).

We also strongly support CMS' proposal to prohibit organizations and agents from setting up future marketing appointments at educational events, for all of the reasons CMS articulates in the preamble. We also strongly support CMS' proposal to prohibit marketing events from taking place within 12 hours of the educational event in the same location. As CMS notes, this will alleviate pressure or obligation beneficiaries may feel into staying for marketing events offered at the conclusion of educational events. CMS should not be swayed by any arguments from the agent/broker community that reinstating these barriers will be an inconvenience for beneficiaries (rather than themselves). As CMS notes, "If a beneficiary attends an educational event and wants further information about a specific MA or Part D product, the beneficiary can go to a marketing event or ask for a one-on-one appointment either in person or through communications technology" (p. 79530). As CMS notes, a 12-hour window will help give beneficiaries "sufficient time to think about the impartial and factual information provided at the educational event" as opposed to a short window of time permissible under current rule.

- Prohibiting personal marketing appointments from taking place until after 48 hours have passed since the time the Scope of Appointment (SOA) was completed by the beneficiary

We support CMS' proposal to codify this requirement and the removal of the "when practicable" exception. We agree that such exception essentially creates a gaping loophole: "We believe 'when practicable' nullifies the purpose of the 48 hour timeframe, given the many reasons that might be cited for why waiting the full 48 hours is not 'practicable'" (p. 79531).

If, as an agent or broker might complain, a beneficiary is right up against an enrollment deadline, such as the end of the annual enrollment period in less than 48 hours, this would not justify waiving the 48 hour period as any sales discussions during this time would be even more ripe for high-pressure sales tactics. An agent or broker in this situation should forgo the commission and refer the individual to 1-800-MEDICARE if no local SHIP is able to assist in time.

As discussed below, we urge CMS to consider narrowing the scope of appointment form (and correspondingly what can be discussed during in-person visits) to exclude ancillary health related products.

- Limiting the ability of plans and agents to contact prospective enrollees beyond 6 months from the time they submit a Scope of Appointment (SOA) or Business Reply Card (BRC)

We strongly agree with CMS that a beneficiary's permission to allow contact by an MA organization/Part D sponsor or a TPMO is not, and should not be open-ended. We urge CMS, though to make the permissible period of contact shorter than the proposed 6 months.

Under the 6 month proposal, an agent/broker who secures an SOA or BRC in October would be able contact a beneficiary across both the annual election period through December 7 and the MA-Open Enrollment Period (January through March) of the following year, providing the salesperson with significant incentive to target and contact beneficiaries across both enrollment periods. We urge CMS to consider a time limit of 3 months, or a current enrollment period, if applicable. As CMS notes, “Beneficiaries who request information regarding MA organizations/Part D sponsors are requesting information at that present time” (p. 79531). Similar to CMS’ point that if a beneficiary wants contact from the agent beyond this period, the agent can secure new permission to do so.

- Requiring website provider directories be searchable by all required elements (for example, name, phone number, address)

We support CMS’ effort to assist beneficiaries in finding particular providers. We support the proposals in section III.A.3 to require organizations to include providers’ cultural and linguistic capabilities and identify certain providers waived to treat MOUD. In addition, there must be way for plans to identify for enrollees when a contracted provider is no longer taking new patients.

- Requirement that agents explain the effect of an enrollee’s enrollment choice on their current coverage whenever the enrollee makes an enrollment decision

CMS’ explanation of findings resulting from an in-depth review of 1-800-MEDICARE complaints, including agent/brokers omissions or misleading statements, comports with what we hear from Medicare beneficiaries. We strongly support CMS’ proposal to add “effect on current coverage” to the Pre-Enrollment Checklist (PECL), as well as a requirement that agents to discuss the PECL during an enrollment call.

We note that the current standardized PECL form (at Appendix 1 of the MCMG) currently does not address utilization management, including prior authorization. Given all of the challenges MA enrollees face with prior authorization, as addressed earlier in this proposed rule, this topic should be addressed in the PECL. In addition, while there is a prompt to review the provider directory in order to ensure one’s providers contract with the plan, it should be disclosed that a provider can be terminated from the plan’s network (or leave) the plan mid-year. This should be accompanied by a statement that an enrollee has a right to seek care outside of a plan’s network when an in-network providers or benefits is unavailable or inadequate to meet an enrollees’ medical needs, as discussed in section III.C. of this proposed rule, above. In addition, the checklist include a specific requirement that, if the prospective enrollee is a dual eligible, the plan or broker must provide a rudimentary explanation of whether benefits offered by the plan duplicate benefits already available to the individual through Medicaid.

In order to ensure that agents and brokers do not continue to mislead or omit required information, CMS must ensure that this provision is enforced. We assume that such discussions would be recorded under current rules, which should help with respect to accountability. We also suggest that if it is found that an agent or broker did not review the requisite material, or materially mislead an individual concerning the content or subject matter of the PECL, that plans be forced to withhold any commissions earned from the sale of that product to the affected

individual. Without teeth to enforcement and oversight, misconduct will likely continue at an unacceptable rate.

One way to enhance oversight and enforcement of agent/broker conduct would be to require that agents and brokers sign an attestation form that whatever product is being sold is appropriate for that beneficiary. Such an attestation is currently required for the sale of Medigap (Medicare supplemental insurance policies).

The Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act⁴⁵ includes “Section 18. Requirements for Application Forms and Replacement Coverage.” Section 18, in turn, includes a “NOTICE TO APPLICANT REGARDING REPLACEMENT OF MEDICARE SUPPLEMENT INSURANCE OR MEDICARE ADVANTAGE.” The language currently states:

STATEMENT TO APPLICANT BY ISSUER, AGENT [BROKER OR OTHER REPRESENTATIVE]:
I have reviewed your current medical or health insurance coverage. To the best of my knowledge, this Medicare supplement policy will not duplicate your existing Medicare supplement or, if applicable, Medicare Advantage coverage because you intend to terminate your existing Medicare supplement coverage or leave your Medicare Advantage plan. The replacement policy is being purchased for the following reason (check one):
 Additional benefits.
 No change in benefits, but lower premiums.
 Fewer benefits and lower premiums.
 My plan has outpatient prescription drug coverage and I am enrolling in Part D.
 Disenrollment from a Medicare Advantage plan. Please explain reason for disenrollment. [optional only for Direct Mailers.]
 Other. (please specify) _____

The language of the Medigap attestation, which requires the review and signature of the selling agent or broker and an identification of the reason for the purchase, could be modified to reflect the sale of an MA or Part D plan. Requiring such an attestation for the sale of MA and Part D plans would both provide additional accountability of the selling agent, and opportunity for the Medicare beneficiary to weigh the effect of their enrollment decision.

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

We support this proposal and agree with CMS that “By requiring all plans to list certain benefits in the same location and in a specified order, beneficiaries will be able to more easily compare benefits across different plans and in a more standardized way. The ability for beneficiaries to

⁴⁵ See the website of the National Association of Insurance Commissioners (NAIC), Fall 2022 (see p. 88): https://www.google.com/url?client=internal-element-cse&cx=012416555441880592692:n8fkiw-ozik&q=https://content.naic.org/sites/default/files/model-law-651.pdf&sa=U&ved=2ahUKEwjBmoG_3Yv9AhXfNEQIH5ZkBz8QFnoECAQQAQ&usg=AOvVaw3HdhScjLctMaamBJbEnjfx.

review and compare benefits across different MA Plans will assist beneficiaries in making a more informed health care choice” (p. 79532).

We also support CMS’ proposal to prohibit plans from modifying the standardized non-renewal notice.

- Modification of certain disclaimers by third party marketing organizations (TPMOs) to add SHIPs as an option for beneficiaries to obtain additional help and to list or mention all of the MA organization or Part D sponsors that they sell

We support CMS’ proposal to modify required TPMO disclaimers when the TPMO does not sell all MA or Part D plans in a service area as well as inclusion of a reference to SHIP programs.

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

We agree with CMS that MA organizations and Part D sponsors appear to be reactive instead of proactive in addressing inappropriate agent and broker behavior. We also share CMS’ concern that inappropriate behavior by agents and brokers is not being sufficiently addressed and corrected by MA organizations and Part D sponsors.

We support CMS’ proposal to require plan sponsors to establish and implement an oversight plan that monitors agents and broker activities. In order to make such a plan effective, however, CMS should mandate sanctions that plans should impose on agents and brokers when inappropriate behavior is identified (e.g., withholding commissions is likely more effective at correcting conduct than re-education). Plans must also be incentivized to provide adequate oversight through the threat of sanctions for non-compliance.

- Requirement that all agents and brokers go through a CMS-developed list of items that must be asked or discussed during the marketing and sale of an MA or Part D plan

We strongly support CMS’ proposal to “requir[e] an MA organization or Part D sponsor ensure that the agent’s/broker’s sales call goes over each CMS required question or topic, including information regarding primary care providers and specialists (that is, whether or not the beneficiary’s current providers are in the plan’s network), prescription drug coverage and costs (including whether or not the beneficiary’s current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs” (p. 79534).

As noted concerning CMS’ proposal about the PECL, discussed above, the topics to be discussed must include MA plans’ use of utilization management, including prior authorization, particularly given all of the challenges MA enrollees face with prior authorization, as addressed earlier in this proposed rule. In addition, with respect to network providers, it should be disclosed that a provider can be terminated from the plan’s network (or leave) the plan mid-year. This should be accompanied by a statement that an enrollee has a right to seek care outside of a plan’s network if care is unavailable through the plan. As noted in our comments to the PECL proposals, adequate oversight and enforcement will be necessary to effectuate this provision.

We also encourage CMS to consult beneficiary advocates and other stakeholders when drafting the proposed sub regulatory guidance that would flesh out more detailed questions and areas to be covered based on these general topics.

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

We support CMS' position that it will retain the requirement that TPMOs, including agents and brokers, regardless of their size, must record calls. We believe this stance is warranted by CMS' findings (as disclosed in its FAQ for Contract Year 2023 Medicare Advantage Marketing Policies) that in the agency's review of recorded calls, "The agents failed to provide the beneficiary with the necessary information or provided inaccurate information to make an informed choice for more than 80 percent of the calls reviewed."

CMS proposes to limit calls that must be recorded from all calls to only those calls regarding sales, marketing, and enrollment. We agree that this proposal is reasonable, but urge CMS to establish procedures to ensure that TPMOs, agents and brokers do not circumvent this requirement (for example, claim that they did not record a call because it did not start out as a sales, marketing or enrollment call but such actively was eventually conducted).

We further support CMS' proposal to require recording of all calls occurring via web-based technology.

- Requirement that personal beneficiary data collected by a TPMO may not be distributed to other TPMOs

We strongly agree with CMS' assertions about beneficiary expectations when connecting with a particular company that their information will not be transferred or sold to other entities who in turn contact them, relying on the initial inquiry as a form of permission. We firmly agree with CMS that "We do not believe beneficiaries knowingly give their permission to receive multiple calls from multiple different entities on the basis of a single call made by a beneficiary" (p. 79535). We also agree that inconspicuous disclaimers allowing such conduct is misleading. We therefore strongly support CMS' proposal that personal beneficiary data collected by a TPMO may not be distributed to other TPMOs.

If a TPMO or other entity wishes to refer an individual to another TPMO or entity that could, in their view, better serve the person, specific and direct consent to do so should be obtained, rather than reliance on a lengthy and/or hidden disclaimer, or back-channel trafficking in individuals' personal information without their knowledge or consent. Beneficiary autonomy and ability to direct how from whom they get information should take precedence over the business interests of lead generating companies and those who use or purchase their information.

As stated above, the Center applauds CMS for addressing many of the causes of marketing misconduct and confusion. We support all of the proposals CMS offers, some with modification. There are other steps that CMS should take in order to further enhance consumer protections. Some of these measures are described in a section at the end of these comments.

R. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

CMS states that it “has observed decreasing eligibility rates and near-universal convergence among Part D sponsors to the most restrictive criteria currently permitted. Due to the increasing cost threshold and variations in the targeting criteria implemented by sponsors, Part D enrollees with more complex drug regimens who would benefit most from MTM services are often not eligible. In addition, enrollees with equivalent patient profiles may or may not be eligible for MTM depending on the criteria their plan requires” (p. 79453). We support CMS’ effort to “promote consistent, equitable, and expanded access to MTM services.” (p. 79453)

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

The Center supports CMS’ proposal to limit the number of PDP contracts under which a Part D sponsor or its parent organization (as defined in § 423.4), directly or through subsidiaries, can offer individual market plan benefit packages in a PDP region to one contract per region. Navigating the Medicare marketplace and choosing a Part D plan is daunting for beneficiaries in the best of circumstances. A proliferation of plans without substantial differences renders this decision even more difficult. We urge CMS to similarly limit the number of plans Medicare Advantage plan sponsors can offer.

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

B. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2)

The proposed rules propose four new definitions of I-SNPs, but essentially just codify subregulatory guidance now found in the Medicare Managed Care Manual, Chapter 16b, section 20.3.

As advocates for Medicare beneficiaries, we urge CMS to promulgate regulations providing greater protection for beneficiaries, particularly in light of (1) the large and increasing number of enrollees in I-SNPs (96,972 in 271 separate I-SNPs, according to CMS, 87 Fed. Reg. 79567), (2) evidence identified by the Medicare Payment Advisory Commission (MedPAC) in 2013 that I-SNPs are prescribing inappropriate medications and could be denying beneficiaries needed hospital care, and (3) the focus of the nursing home industry in operating and controlling I-SNPs.

MedPAC

In 2013, MedPAC supported permanent reauthorization of I-SNPs, but made two disturbing comments about the care provided by I-SNPs.⁴⁶

First, MedPAC found that I-SNPs “have higher rates than regular MA plans for the use of potentially harmful drugs among the elderly and the use of drug combinations with potentially

⁴⁶ (Mar. 2013), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-14-medicare-advantage-special-needs-plans-march-2013-report-.pdf

harmful interactions.”⁴⁷ MedPAC excused these higher rates of inappropriate drugs and drug combinations by noting “their higher rates of monitoring of persistently used drugs suggest that drugs with potential interactions or adverse effects are also being closely monitored.”⁴⁸ Additional monitoring is not reassuring when residents continue to receive inappropriate drugs.

MedPAC’s only other comment is the note that I-SNPs have “fewer hospital readmissions than would be expected given the clinical severity of their enrollees.”⁴⁹ MedPAC then leaps to the conclusion that “I-SNPs’ performance in hospital readmissions rates is an important measure of whether they provide a more integrated delivery system.”⁵⁰ That conclusion is not necessarily true. I-SNPs may simply be denying hospitalization for residents who need to be hospitalized or not paying for hospital care. MedPAC’s only support for its conclusion is the statement, without supporting citation, that “I-SNPs attempt to reduce hospital and emergency department utilization through care management and by emphasizing the provision of primary care.”⁵¹

These observations by MedPAC about inappropriate medication use and fewer hospitalizations suggest that more beneficiary protection is needed, as discussed below.

Nursing homes’ interest in participating in I-SNPs for financial gain

I-SNPs are increasingly led and controlled by long-term care facilities. The American Health Care Association (AHCA) reports that “LTC provider-led I-SNPs grew to 36 percent of all I-SNPs in 2022, with almost one-third of the total number of I-SNP beneficiaries in LTC provider-led plans.”⁵²

AHCA reported that provider-led I-SNPs increased from 52 of 57 I-SNPs in 2015 to 110 of 174 I-SNPs in 2021.⁵³

⁴⁷ *Id.* 321

⁴⁸ *Id.*

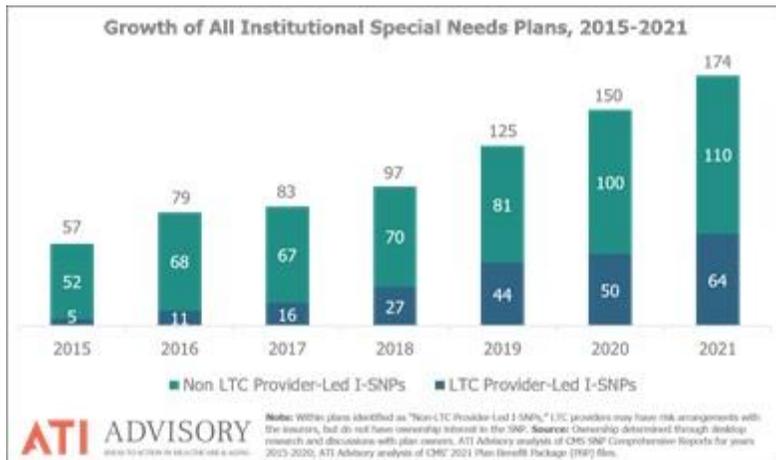
⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² AHCA, Long Term Care Provider-Led Special Needs Plans: A Solution for Accountable Care, https://www.ahcancal.org/Advocacy/IssueBriefs/Provider%20Led%20SNP%20Business%20Case%20One%20Pager_CB%202022_Final.pdf#search=I%20DSNP

⁵³ AHCA, Population Health Management, <https://www.ahcancal.org/Reimbursement/Pages/Population-Health-Management.aspx>



These numbers reflect dramatic increases in provider-led I-SNPs. Between 2016 and 2018, the number of provider-led I-SNPs doubled from 12 to 24 and the number of enrollees in provider-led I-SNPs more than doubled from 5,014 to 12,488.⁵⁴

AHCA describes forming a Population Health Management (PHM) Council in 2019 in order “to convene and support long LTC providers who are leading in PHM initiatives through advocacy, education, and quality improvement data.”⁵⁵ AHCA identifies four organizations – AllyAlign Health, American Health Plans, Longevity Health Plan, and PHHP – “whose sole or primary purpose is to partner with LTC providers to support LTC provider ownership interests in PHM models.”⁵⁶

Nursing homes’ interesting in operating I -SNPs is financial. On AHCA’s website, American Health Plans writes:

American Health Plans’ provider-owned I-SNPs allow nursing home owners and operators to take control of the LTC residents and realize 100 percent of the shared savings associated with execution of the model of care.⁵⁷

Facility level financial returns: 100 percent shared savings

For too long, the concept of risk-based reimbursement meant an upside to other providers and a downside for nursing home owners and operators. American Health Plans has changed that dynamic. Their members are your residents and 100 percent of the shared savings generated

⁵⁴ Anne Tumlinson and Elizabeth Walsh, “Long-Term Care Providers Drive Growth in Special Medicare Advantage Plans,” *Skilled Nursing News* (Dec. 18, 2018), <https://skillednursingnews.com/2018/12/long-term-care-providers-drive-growth-special-medicare-advantage-plans/>

⁵⁵ AHCA, Population Health Management, <https://www.ahcancal.org/Reimbursement/Pages/Population-Health-Management.aspx>

⁵⁶ AHCA, Population Health Management, <https://www.ahcancal.org/Reimbursement/Pages/Population-Health-Management.aspx>

⁵⁷ AHCA, American Health Plans, <https://www.ahcancal.org/Reimbursement/Documents/PHM/American%20Health%20Plans%20Overview.pdf#search=%2DSNP>

through great clinical results is paid to the nursing facilities. These are savings your facility has earned. American Health Plans ensures you keep them within the facility.

The piece concludes:

American Health Plans: control your future by controlling the Medicare premium

As nursing home owners themselves, American Health Partners appreciates the challenges of clinical resources and cash flow. However, their experience owning and operating Medicare Advantage Plans since the inception of the program in 2004 has allowed them to realize the clinical and financial power of controlling the Medicare premium for their nursing home residents. They want to partner with you to bring the clinical program and financial upside to your facilities as well.

MedPac reported in March 2019 that I-SNPs had average margins of 9.4% (compared to MA plan's average margins of 2.7%).⁵⁸

Center for Medicare Advocacy's Concerns about I-SNPs

I-SNPs are Medicare Advantage plans, which means that they are responsible for all of the health care costs of their members that they cover. The I-SNP receives the full Medicare payment for plan enrollees and controls whether and how Medicare dollars are spent. The CEO of AllyAlign, a company that helps providers, including SNFs, implement provider-sponsored managed care plans, described the model in 2019: "The construct is to grab the [Medicare] premium dollar directly if you're an LTC provider, and then manage in the best interests of the patient."⁵⁹ When the I-SNP is owned by the nursing home, there is an inherent conflict of interest because the plan, acting as an insurer, can deny coverage of expensive care, such as care in its own skilled nursing facility.

In 2017, Kaiser Health News highlighted the conflict of interest in a report about an Erickson Living continuing care retirement community (CCRC) in Maryland, which had an I-SNP, called Erickson Advantage, solely for its community's residents. Kaiser described a resident in the retirement community, who was sold an Erickson Advantage plan by an Erickson nurse. After the woman returned to the community from the hospital, the I-SNP limited, and then denied, Medicare coverage of her stay in the skilled nursing facility (SNF) part of the CCRC.⁶⁰ Although the Erickson Advantage plan reversed its noncoverage decision after being contacted by the reporter, Kaiser Health News described the experience of a second resident with an Erickson

⁵⁸ MedPAC, *Report to the Congress: Medicare Payment Policy*, 358, 357, respectively (Mar. 2019), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_ch13_sec.pdf

⁵⁹ Maggie Glynn, "AllyAlign CEO: I-SNPs Will Form 'Permanent Pillar' in Changing Skilled Nursing World," *Skilled Nursing News* (Jan. 27, 2019), <https://skillednursingnews.com/2019/01/allyalign-ceo-i-snps-will-form-permanent-pillar-in-changing-skilled-nursing-world/>

⁶⁰ Jordan Rau, Kaiser Health News, "Nursing Homes Get Into the Insurance Business," *U.S. News & World Report* (Jul. 12, 2017), <https://www.usnews.com/news/healthcare-of-tomorrow/articles/2017-07-12/nursing-homes-get-into-the-insurance-business>; also available at <https://khn.org/news/nursing-homes-move-into-the-insurance-business/>

plan in Massachusetts, who similarly had her SNF coverage limited by the Erickson plan. After 11 days in the community's SNF, the 98-year-old resident was charged a daily rate of \$463 (later increased to \$483) for her SNF stay. Kaiser reported that an administrative law judge upheld the Erickson plan's determination that the woman's SNF stay was not covered by Medicare, "based on the testimony from the nursing home staff – all Erickson employees." At the time of the Kaiser article, the CCRC's bill for the enrollee resident's SNF stay was \$30,000, and increasing daily.

F. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (§ 422.101)

The Center recommends that CMS require each D-SNP to make public its model of care. This would help beneficiaries and other stakeholders determine whether a given D-SNP is fulfilling obligations outlined in its own model of care.

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

SEPs are critical for beneficiaries faced with challenging circumstances such as disasters or other public emergencies. The Center appreciates CMS' effort to establish an automatic incident end date that would apply if no end date for the period of disaster or emergency is otherwise identified within one year of the start of the SEP. We encourage CMS, though, to extend the SEP six months (rather than the proposed two) after the incident end date, thereby providing additional time for beneficiaries as they cope with the ongoing effects or aftereffects of a disaster or emergency.

U. Shortages of Formulary Drug Products During a Plan Year (§ 423.120)

We appreciate CMS' attention to the impact of drug shortages on beneficiaries and support the proposal to enable beneficiaries to obtain a therapeutic equivalent or nonformulary alternative without having to go through the nonformulary exceptions process. We urge CMS, however, to prohibit PDP sponsors from charging enrollees the difference in price between the formulary drug product and the therapeutic equivalent or nonformulary alternative. Beneficiaries should not be held financially responsible for systemic problems that are beyond their control.

AD. Crosswalk Requirements for Prescription Drug Plans (§ 423.530)

The Center appreciates CMS' efforts to standardize the process and conditions under which PDP sponsors can transfer enrollees into another PDP's plan benefits package from year to year when such enrollees have made no other election. For beneficiaries, the impact of such crosswalks can extend far beyond the cost of the monthly premium. Thus, when a PDP sponsor chooses to crosswalk in a consolidated renewal scenario, the sponsor should be required to consider overall out-of-pocket costs and the formulary. We also encourage CMS to grant a special enrollment

period (SEP) right to beneficiaries in such scenarios, similar to those in nonrenewing or terminating PDPs.

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

The Center for Medicare Advocacy is generally supportive of efforts to increase equity within Medicare and Medicare Advantage. In turn, we support the notion behind creating the Health Equity Index Reward. The MA Star Ratings, however, are fundamentally flawed, and while they are promoted as tool for consumer comparison of plans, they do not adequately do so and must be overhauled in a manner that strengthens public reporting on plan quality and variation.

As we stated in our comments to CMS' MA RFI, a June 2022 House Energy & Commerce Committee briefing memorandum⁶¹ for a hearing concerning MA oversight summarized issues relating to the MA Star Ratings and quality bonus program:

The quality bonus program with its star rating system is intended to be a source of information about the quality of MA plans for beneficiaries. However, MedPAC has found that the program, which cost \$6 billion in 2019 and is projected to cost \$94 billion over 10 years, is flawed. MedPAC found that the way that measures are examined and reported are not particularly useful as an indicator of quality of care provided in a beneficiary's local area. Additional studies also suggest that the MA quality bonus program has not improved plan quality [citations omitted].

CMS must overhaul or replace the Star Ratings system and corresponding bonus payment program.

Conclusion

We appreciate the opportunity to submit these comments. For additional information, please contact David Lipschutz, Associate Director at DLipschutz@medicareadvocacy.org or (202)293-5760.

Sincerely

David Lipschutz, JD
Associate Director/Senior Policy Attorney
Licensed in CA and CT

Toby Edelman, Ed. M., JD
Senior Policy Attorney
Licensed in Washington DC

Cinnamon St. John, MPA, MA
Senior Health Policy Specialist

⁶¹Memorandum to Subcommittee on Oversight and Investigations Members and Staff from Committee on Energy & Commerce Staff Re: Hearing on "Protecting America's Seniors: Oversight of Private Sector Medicare Advantage Plans" (June 24, 2022), available at: https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Briefing_Memo_OI_Hearing_2022.06.28_0.pdf.