

Submitted via e-mail to: AdvanceNotice2019@cms.hhs.gov.

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter (“Draft Call Letter”)

On behalf of the Regulatory Relief Coalition, including the undersigned professional organizations, we are pleased to have this opportunity to comment on the Draft Call Letter. Our comments focus on MAOs’ growing use of prior authorization (PA) requirements as a precondition of coverage of Part B services, including a wide range of physicians’ services.

The Draft Call Letter explicitly recognizes the need for MAOs to make PA processes and requirements transparent and to adhere to regulatory timeframes and appeal procedures. We applaud CMS for including these provisions in the Draft Call Letter: These provisions lay the groundwork for a comprehensive approach to PA-related issues and constitute a strong start for CMS efforts in this area.

CMS’ focus on the burdens posted by PA is extremely timely. Notably, associations representing health plans, including the Association of Health Insurance Plans (AHIP) and Blue Cross/Blue Shield Association (BC/BS) themselves recently recognized the need to streamline and simplify prior authorization processes. These associations, along with a number of provider groups, have started by adopting the **Consensus Statement on Improving the Prior Authorization Process**¹ which sets forth a number of principles for the design and implementation of PA programs. We believe that CMS has the potential to play a critical role in ensuring that these principles become the industry standard, ultimately benefiting patients, providers and health plans alike. Our recommendations regarding the Draft Call Letter set forth below are consistent with the principles endorsed by the associations representing the managed care industry in the Consensus Statement.

While we applaud CMS’ commitment to ensure additional transparency and adherence to timelines and other process requirements as described in the Draft Call Letter, we strongly believe that, to ensure that PA restrictions do not pose inappropriate barriers to access, additional complementary action is needed. The most important of step—the issuance of comprehensive PA guidelines to MAOs—does not appear to fall within the scope of the Draft Call Letter, and we look forward to continued discussions with CMS regarding the issuance of such guidelines. However, in addition to calling for transparency and adherence to “organization determination” regulatory requirements, we urge CMS to address a number of other aspects of the use of PA by MAOs in the final 2019 and subsequent Call Letters, as further described below.

¹<https://www.mgma.com/getattachment/Government-Affairs/Issues-overview/Health-Information-Technology/Administrative-Simplification/Administrative-Simplification/Finalized-PA-consensus-statement-120717-logos.pdf>.

All of our comments could be addressed by adding the underscored language at the end of the section of the Draft Call Letter entitled “Transparency and Timeliness with Prior Authorization Processes” (page 193):

Transparency & Timeliness with Prior Authorization Processes

. . . Therefore, these requests are subject to applicable pre-service organization determination adjudication timeframes and notice requirements under the MA regulations, and any determination denying payment for the service involved (including any denial based on medical necessity, beneficiary eligibility, plan exclusion or other reason) must be made within these timeframes and are subject to the appeals process. See 42 CFR §§422.568 and 422.572.

Plans are also reminded that Medicare regulations require MAOs to comply with HIPAA administrative simplification rules set forth at 45 CFR parts 160, 162, and 164). The HIPAA regulations require that all health plans (including but not limited to MAOs) use a particular IT standard format (the 278 Standard)² for all prior authorization electronic (referral certification and authorization) transactions effective on and after January 1, 2012, and are required to use the applicable data content and data condition requirements of the 278 Standard for all direct data entry transactions. 42 CFR §162.1302, 42 CFR § 162.923(b). Failure to comply with HIPAA administrative simplification requirements constitutes a violation of MA regulations

Plans are reminded that they are required to cover all services that are covered; under Part A and Part B of Medicare, and that prior authorization requirements may not impose an inappropriate barrier to access. For example, regular review of the list of medical services and prescription drugs that are subject to prior authorization requirements can help identify therapies that no longer warrant prior authorization due to, for example, low variation in utilization or low prior authorization denial rates. CMS plans to enforce PA transparency and other regulatory requirements through administrative review of plan marketing materials, plan audits, and other tools that CMS has available to it.

A. PA Decisions as Pre-Service “Organization Determinations”

² Formally, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 - Health Care Services Review - Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review - Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1.

We appreciate CMS' calling MAOs' attention to the fact that PA determinations constitute "pre-service organization determinations" under applicable regulations and as such are subject to regulatory adjudication timeframes and notice requirements.

We believe that CMS has the opportunity to significantly improve the PA process by clarifying an important issue related to pre-service determination timeframes in the final Call Letter. MAOs generally take the position that services that are approved through the PA process may be denied subsequently—beyond the 14-day timeframe for standard determinations and the 72-hour timeframe for expedited determinations--on the basis of deficiencies unrelated to the medical necessity of the items or services involved., including, for example, enrollee eligibility or a coverage exclusion in the enrollee's benefit package. As a result, a physician may go through a long and time-consuming PA process, obtain an approval, provide the service in good faith reliance on the approval, only to find out at a later date that coverage and payment for the service is denied. Conversely, an enrollee's request for PA may be denied, go through numerous appeals, and ultimately approved, only to have coverage denied or limited for reasons unrelated to medical necessity. For the reasons set forth in the attached legal memorandum (Attachment A), we believe that this practice is inconsistent with regulatory requirements imposing specific timeframes for making organization determinations.

Recommendation: We urge CMS to include in the Final Draft Call Letter a statement reminding MAOs that since a request for PA is a request for an organization determination, any determination affecting payment for the item or service involved must be made within the regulatory timeframes and included in any denial notice.

B. Attestation of Compliance with Administrative Simplification Requirements.

One of the major administrative barriers for providers who serve MA beneficiaries is the myriad of forms used by the various plans to implement PA processes. The MA regulations (42 CFR §422.504(h)(2)) specifically require MAOs to comply with HIPAA administrative simplification regulations. These HIPAA regulations require that all health plans (including but not limited to MAOs) use a particular IT standard format (the 278 Standard)³ for all PA electronic transactions⁴ (in HIPAA parlance, "referral certification and authorization" transactions) effective on and after January 1, 2012.⁵ It is our understanding that, despite this regulatory requirement, many health plans are not processing electronic transactions in accordance with the 278 Standard. In addition, under the HIPAA administrative simplification rules with which MA plans are required to comply under 42 CFR §422.504(h)(2), MA plans that process PA requests through proprietary websites are required to mirror the content of the 278 Standard, a requirement that is not being honored.

³ Formally, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 - Health Care Services Review - Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review - Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1.

⁴In HIPAA parlance, "referral certification and authorization" transactions

⁵ 45 CFR §162.1302.

Recommendation: We urge CMS to include in the PA section of the final Call Letter a reminder that PA processes are required by regulation to comply with all HIPAA requirements, including HIPAA administrative simplification requirements, which call for the use of the EDI 278 Health Care Services Review Information Transaction Standard for all ““referral certification and authorization” transactions” and the use of Standard 278-equivalent content for propriety websites. MAOs should be reminded that failure to comply with HIPAA administrative simplification requirements constitutes a violation of MA regulations. .

C. Star Ratings

We believe that MA plans’ performance in conducting PA reviews of medical services should be subject to the same public disclosure and governmental scrutiny as Prescription Drug Plans (PDPs’) performance in conducting PA reviews of prescription drugs. In last year’s Draft Call Letter, CMS proposed adopting a new display measure under which each Part D plan sponsor’s performance in applying PA, step therapy (ST), quantity limits and similar utilization controls is made publicly accessible and to develop performance measures related to utilization controls as part of PDPs’ “beneficiary access” star ratings.⁶ Similar public disclosure should be applied to MA plans’ performance in implementing PA and other utilization controls for medical services.

Recommendation: We urge CMS to work with affected providers, patients, and MAOs to develop a PA-related “access to care” display measure and for inclusion in MA plans’ star ratings.

D. Implementation of Draft Call Letter Provisions related to Transparency

The Draft Call Letter reminds MAOs that they should be transparent and provide adequate notice of any coverage restrictions, such as PA requirements, to providers and enrollees by specifying the existence of any coverage restrictions, including what information is needed when submitting a PA request, in the plan’s Evidence of Coverage (EOC), their contracts with providers and additional provider communications/materials (e.g., provider manuals). The Draft Call Letter also reminds MAOs to make PA request forms available and easily accessible; to deliver timely decisions on PA requests; and subject PA requests to applicable pre-service organization determination adjudication timeframes and notice requirements under the MA regulations. We very much appreciate CMS’ inclusion of these requirements in the Draft Call Letter.

Section 1852(c)(1)(G) of the Social Security Act specifically requires that each MAO disclose, in clear, accurate, and standardized form to each enrollee:

⁶ It is our understanding that, under this proposal, the results of the Formulary Administration Analysis (FAA) program would be publicized. Under this program, CMS evaluates a sample of rejected claims to determine whether Part D sponsors (including Medicare Advantage Plans offering Part D benefits) are appropriately adjudicating Part D drug claims, assigning a pass or fail to each sample claim depending on the appropriateness of the rejection.

Rules regarding prior authorization or other review requirements that could result in nonpayment.

Such disclosure must be made at the time of enrollment and at least annually thereafter. This requirement is also reflected in the implementing regulations.

Recommendation: Since the statute and regulations both require that rules regarding PA be disclosed in “standardized format,” we recommend that CMS provide to MAOs the language that they are required to include in the plan’s primary marketing and EOC.

Recommendation: We urge CMS to enforce the requirement that MAOs disclose PA restrictions in its EOC, contracts with providers and additional provider communications through the agency’s review of an MAO’s marketing materials, through MA plan audits, and through other enforcement tools that CMS has available to it.

E. Oversight and Audit Focus on PA

Beyond issues related to transparency and adherence to regulatory appeal and notice requirements, we urge CMS to focus its oversight and audit activities on ensuring that MAOs’ PA processes do not establish inappropriate barriers to access, and to include in the final Draft Call Letter a statement placing MAOs on notice that this will be a focus area for audit and oversight in coming years. Last year’s Draft Call Letter and other agency actions suggest that CMS has a growing concern about beneficiary access to prescription drugs as the result of PA and other utilization management tools by Medicare Part D PDPs, but the same audit focus has not been evident with regard to the use of PA to delay or preclude beneficiary access to medical services.

Recommendation: We urge CMS to focus oversight and audit activities on the extent of PA requirements imposed by MAOs and to make this focus clear in the final Call Letter.

Again, we very much appreciate CMS’ responsiveness to our concerns about the use of PA by MAOs, and look forward to working with you to build on the Draft Call Letter’s strong start in addressing this important issue.

Sincerely yours,

American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons and
the Congress of Neurological Surgeons
American College of Rheumatology
American Society of Clinical Oncology
American Urological Association