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10/8/2024

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

**RE: Service Level Data Collection for Medicare Advantage Plans (CMS-10905) (OMB Control Number: 0938-New)**

**SUBMITTED ELECTRONICALLY**

Dear Administrator Brooks-LaSure:

On behalf of the more than 9,000 physiatrists of the American Academy of Physical Medicine and Rehabilitation (AAPM&R), we appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to its intent to collect service level data on Medicare Advantage (MA) determinations and appeals.

AAPM&R is the national medical specialty organization representing physicians who are specialists in physical medicine and rehabilitation (PM&R). PM&R physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability and are experts in designing comprehensive, patient-centered treatment plans. Physiatrists utilize cutting-edge as well as time-tested treatments to maximize function, quality of life, and independence for their patients, and as such are leaders in the field of providing care to the disability community. With their training and expertise, PM&R physicians strive to deliver high-quality, cost-effective rehabilitative care to help patients achieve the highest level of functional ability and quality of life across the continuum of care.

**Prior Authorization Reform**

AAPM&R thanks CMS for its recent regulatory actions to reign in the overreaches of MA organizations that employ utilization management and prior authorization (PA) tools to inappropriately delay and deny care to beneficiaries.

While CMS has taken significant steps to reform the PA process, PA is unfortunately still a serious barrier to care under the MA program, particularly for patients with disabilities and individuals seeking medical rehabilitative care.

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AAPM&R strongly supports public reporting of payer PA data, as transparency has the potential to make the PA process more navigable for both physicians and patients and to improve health outcomes.

In previous comments AAPM&R has strongly encouraged CMS to collect more granular data, rather than in an aggregated format, from payers for all services and procedures at the site of service. This transparency would help CMS better understand the quality of care being provided in each setting, thereby holding MA plans more accountable for their performance.

For example, PM&R physicians report that MA plans frequently deny medically appropriate requests to admit patients for care in the inpatient rehabilitation facility (IRF) setting. MA plans denying medically appropriate requests to admit certain patients for IRF services, despite referrals from treating physicians in acute care hospitals and admission decisions by rehabilitation physicians in IRFs, can be appealed and often are reversed in favor of IRF providers and patients.

While appeals are frequently successful, the delays resulting from inappropriate denials create a "gatekeeper" effect. Many referring acute care hospitals no longer even try to admit MA patients into IRFs, but instead discharge patients directly to lower-intensity levels of post-acute care in spite of patients' needs for intensive, coordinated, hospital-based rehabilitation.

**Reviewer Qualifications**

AAPM&R encourages CMS to collect data on reviewer qualifications when making an initial medical necessity determination, and to require the reporting of the reviewer's clinical background, specific certifications, and previous work experience.

Under current regulations, if an MA plan intends to issue a partial or fully adverse medical necessity decision based on the initial review, the determination must be reviewed by a "physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision." Despite this requirement, MA plans frequently utilize clinicians with little to no training in rehabilitation medicine as reviewers to overrule PM&R physician admission decisions and deny medically appropriate PA requests.

Please consider AAPM&R a resource in your efforts moving forward, and if the Academy can be of further assistance, please contact Chris Stewart, Director of

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Advocacy and Government Relations at AAPM&R, at cstewart@aapmr.org or 202.256.6580.

Sincerely,

Prakash Jayabalan, MD, PhD, FAAPMR
Chair, AAPM&R Health Policy & Legislation Committee

AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

*Submitted Electronically*

October 8, 2024

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-10905

**Re: Agency Information Collection Activities; Proposed Collection; Comment Request – Service Level Data Collection for Initial Determinations and Appeals (CMS-10905)**

Dear Administrator Brooks-LaSure:

On behalf of the American Medical Rehabilitation Providers Association (AMRPA), we write to offer our comments on the Centers for Medicare & Medicaid Services' (CMS) proposed Information Collection Request on Service Level Data Collection for Initial Determinations and Appeals (CMS-10905), published in the *Federal Register* on August 9, 2024. AMRPA is the national trade association representing nearly 800 freestanding inpatient rehabilitation hospitals and rehabilitation units of general hospitals, referred to as inpatient rehabilitation facilities (IRFs). Our members focus on the medical care and functional recovery of some of the most vulnerable Medicare beneficiaries – such as traumatic brain injury, stroke, and spinal cord injury patients. Our member hospitals help patients maximize their health, functional ability, independence, and participation in their communities, so they are able to return to home, work, or an active retirement.

IRFs play a unique and critical role in providing hospital-level medical and rehabilitation care to beneficiaries in Traditional (Fee-for-Service) Medicare and those enrolled in Medicare Advantage (MA) plans. Unfortunately, many individuals face significantly reduced access to inpatient rehabilitation care in the latter program[1], and we have long urged CMS to ensure that all beneficiaries maintain appropriate access to medically necessary covered benefits regardless of their chosen form of Medicare coverage. Meaningfully increasing transparency within the MA program regarding access to care and utilization management has been a key priority for AMRPA and our member hospitals in recent years. We appreciate CMS' focus on advancing data collection so that patients, providers, and policymakers have the information they need to

[1] Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy 298 (March 2017) (finding that MA beneficiaries have one-third the access to IRF care than Traditional Medicare beneficiaries).

**Chris Lee · Chair, AMRPA Board of Directors**
**Vice President & Chief Operations Officer, Madonna Rehabilitation Hospitals**
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address concerns with MA program practices and so that beneficiaries can make fully informed decisions as to their Medicare coverage options.

## I. CMS Proposed Information Collection

Under this proposed Information Collection Request (ICR), CMS seeks to expand the reporting requirements for organizations sponsoring or offering Medicare Advantage health plans ("MA organizations") regarding their use of prior authorization and related utilization management procedures. Specifically, the agency seeks to institute a new quarterly reporting requirement under which MA organizations must report a series of data elements on each initial determination of coverage, including, among others:

- The requested service code(s) and name of the associated service(s),
- The diagnosis code(s) submitted with the request for service(s),
- Whether the determination was processed as a standard or expedited request,
- Whether the provider was contracted with the MA organization (i.e., "in-network" or not),
- The plan's decision on the request (approved or denied),
- The "decision rationale," and
- Whether internal plan criteria were applied.

Plans would also be required to submit data on each appeal (plan reconsideration) that can be connected to the initial determination, including the approval/denial, the processing priority (standard or expedited), the decision rationale upon reconsideration, and the "reviewer qualifications."

CMS had previously indicated the agency was considering expanding data reporting requirements for MA organizations through the Paperwork Reduction Act (PRA) process in the MA final rule for Contract Year 2025.[2] In doing so, the agency cited the importance of CMS better understanding the circumstances in which plans choose whether to pay for a service or item and supporting the agency's critical role in overseeing MA organizations to ensure that enrollees have continued access to care. In this proposed notice, the agency further explains that the proposed ICR would "provide key data on the utilization of benefits, enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits."[3] In our previous comments on the 2025 proposed rule, AMRPA strongly supported these goals, and we continue to do so. **We urge CMS to finalize these and other associated information collections to expand transparency regarding MA organizations' coverage determinations and offer more detailed comments below**.

[2] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE), 89 Fed. Reg. 30,448 (Apr. 23, 2024).

[3] Supporting Statement – Part A, Service Level Data Collection for Initial Determinations and Appeals (CMS-10905, OMB-New), Centers for Medicare & Medicaid Services (Aug. 9, 2024). https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10905

## II. Importance of Service-Level Data Collection

As the burden of prior authorization by MA organizations has grown in recent years, especially with regards to inpatient rehabilitation admissions, AMRPA and many other allied organizations have long called for greater transparency regarding plans' use of these practices and their impact on patient access to care. We appreciate CMS' recent flurry of activity in this area, including the 2024[4] and 2025 MA final rules and the "electronic prior authorization" final rule issued in early 2024,[5] but have raised concerns that certain new requirements have either not gone far enough, or have yet to be sufficiently enforced. AMRPA believes that the proposed service-level data collection contained in this ICR will meaningfully advance both goals.

As we have noted previously to CMS, including in our comments on the electronic prior authorization proposed rule submitted in March 2023 and our response to CMS' January 2024 *Request for Information on MA Data*, the prior authorization transparency metrics currently set to go into effect in 2026 are only mandated at the plan level, aggregated for all items and services. Despite findings that certain services (such as inpatient rehabilitation admissions) have been particularly vulnerable to inappropriate denials and coverage restrictions[6], collecting only aggregate data covering vast swaths of services threatens to limit the utility of any prior authorization data and threatens to obscure any problematic trends for specific services or types of care that CMS must address. By collecting service-specific prior authorization data for each determination that an MA organization makes, CMS will be able to better identify any access concerns and determine whether certain services are denied at an inappropriately high rate (which would be consistent with the reported trends across the post-acute care industry, especially from IRFs).

Furthermore, we appreciate that CMS specifically proposes to collect this data not only on initial determinations, but the first level of appeals as well (i.e., the plan reconsideration process). Independent data analyses have demonstrated that while relatively few MA beneficiaries facing care denials go through the appeals process, the vast majority of those who do appeal are able to get denials overturned, even though the reconsideration process simply involves the same MA organization reviewing the same patient information available at the initial determination stage. Specifically, a recent *KFF* analysis found that from 2019-2022, more than 80% of reconsiderations were fully or partially favorable towards the beneficiary, with those proportions

[4] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 Fed. Reg. 22,120 (April 12, 2023).

[5] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program, 89 Fed. Reg. 8,758 (Feb. 2, 2024).

[6] *See, e.g.*, HHS OIG, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns about Beneficiary Access to Medically Necessary Care (Apr. 2022) (https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf) (finding that IRF services are among the "most prominent" of the service types that MA plans denied despite meeting Medicare coverage rules).

actually increasing in 2022 (the most recent year for which public data was available).[7] We believe such high reconsideration rates indicate serious problems with the level of care and attention that MA organizations use in making initial determinations, and question whether some plans utilize initial denials as a "matter of course" or a tactic to delay and deny care for patients who clearly demonstrate medical need. Collecting robust, service-level data on initial determinations and reconsiderations will allow CMS (and, hopefully, the public and other stakeholders) to better understand these practices and determine what additional policy levers are necessary to ensure MA beneficiaries receive the care to which they are entitled under the Medicare program. We urge CMS to finalize this proposal and quickly begin collecting this information from MA organizations in calendar year 2025.

## III. Specific Data Elements Included in CMS' Proposal

Generally, AMRPA supports the proposed data elements for collection from MA organizations. However, we believe that additional detail should be provided to ensure that the data accurately meets the standard the agency is expecting and provides meaningful information for the end user of such data.

*Processing Priority (Elements I-I and II-E)*

We support the inclusion of this data element, as collection will provide insight as to any trends that may be identified with the outcomes of determinations based on whether a request is processed as standard or expedited. However, we encourage CMS to also collect information on whether an MA organization accepted or denied a requesting provider's stated processing priority. Under the MA regulations for expediting organization determinations[8] and reconsideration requests[9], when a request for an expedited determination is made or supported by a physician, the MA organization "*must provide an expedited determination* if the physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee *or the enrollee's ability to regain maximum function*" (emphasis added). Given the serious injuries, illnesses, or disabilities often preceding inpatient rehabilitation stays, and the importance of timely access to rehabilitation for maximizing functional gains, many requests for prior authorization of IRF admission (and subsequent appeals) are submitted as expedited requests, with the sufficient physician support and justification.

However, in recent months, AMRPA members have increasingly reported that MA organizations are denying such requests for expedited determinations, without any clinical justification, and automatically transferring these requests to be treated as standard determinations. This only leads to additional delays for beneficiaries in need of timely rehabilitation care, especially if the standard determination still results in an initial denial that must be appealed. Collecting

[7] Jeannie Fuglesten Biniek, Nolan Sroczynski, and Tricia Neuman, *Use of Prior Authorization in Medicare Advantage Exceeded 46 Million Requests in 2022* (KFF, Aug. 8, 2024). https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/.
[8] 42 C.F.R. § 422.570(c)(2).
[9] 42 C.F.R. § 422.584(c)(2).

information directly from MA organizations on how frequently they utilize these tactics and requiring plans to report a rationale for such denial, would help shine a light on whether certain services or settings face a disproportionate rate of processing priority denials. We urge CMS to add to the proposed collection to better capture this information.

*Decision Rationale (Elements I-P and II-F)*

CMS proposes to collect the "decision rationale" for both initial determinations and plan reconsiderations. However, this data element is not further defined, and CMS indicates in the supporting statement that the agency is specifically soliciting feedback on "how health plans can most efficiently provide information to CMS on their decision rationales."[10] Currently, MA organizations are required to "state the specific reasons for the denial" when the organization denies a service or item and communicate this to the beneficiary in writing.[11] However, providers and patients have long reported that the denial notices provided by MA organizations do not reasonably inform the beneficiary of the specific reasons for denial and often vaguely cite large swaths of regulation or include boilerplate language that does not indicate any individualized assessment of the patient's medical and functional needs. Especially for inpatient rehabilitation care, for which the coverage guidelines in Medicare statute and regulations are robust and explicitly stated, such ambiguous decision rationales are insufficient and only lead to additional confusion and delays while patients and providers attempt to address any perceived deficiencies through the appeals process.

While we recognize that changes to the existing beneficiary notification process may be outside the scope of this ICR, we urge CMS to carefully consider whether the current regulations are sufficient and more clearly define what level of detail is needed for plans to fulfill their substantive requirements with respect to decision rationales, whether the recipient is CMS, the patient, or the provider.

*Reviewer Qualifications (Element II-G)*

CMS proposes to collect "reviewer qualifications" when a plan makes a determination at the reconsideration level. Under the 2024 MA final rule, when an MA organization expects to issue an adverse medical necessity decision on a prior authorization request, the decision must be reviewed by "a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue."[12] CMS explicitly discussed the application of this requirement to inpatient rehabilitation admissions in the preamble to the final rule, stating that "the plan reviewer reviewing a request for IRF care would need to have the background and knowledge to determine that the enrollee's medical condition requires intensive rehabilitation, continued medical supervision, and coordinated care. Accurately assessing the enrollee's diagnosis, conditions, and functional status requires clinical

[10] Supporting Statement – Part A, Service Level Data Collection for Initial Determinations and Appeals (CMS-10905, OMB-New), Centers for Medicare & Medicaid Services (Aug. 9, 2024). https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10905.
[11] 42 C.F.R. § 422.568(e)(2).
[12] 42 C.F.R. § 422.566(d).

expertise… and could be made, for example, by a physical medicine and rehabilitation doctor, a neurosurgeon, a physical therapist, or a rehabilitation nurse."[13]

Since this rule has gone into effect, however, AMRPA members have consistently reported that denials are issued without appearing to meet this standard. For example, some MA organization reviewers denying IRF admissions have reported specialties wholly unrelated to rehabilitation, without any attempt to justify their relevant expertise, including physicians specializing in plastic surgery, anesthesiology, internal medicine, family medicine, and pediatric gastroenterology. Even more concerning, plans have lately appeared to change their processes to conceal the qualifications of their reviewers, with increasing numbers of IRFs now reporting that reviewing clinicians are refusing to provide information on their specialty, expertise, or credentials at all. Some hospitals have even reported that MA organization representatives have communicated that their legal compliance departments have made it a policy not to provide any information on the reviewing clinicians, even their names.

We believe these trends underscore just how critical it is that CMS finalize this data collection so that the agency can appropriately carry out its oversight and enforcement responsibilities over plan compliance. Providing additional clarity regarding the definition of the data element (i.e., specialty of reviewing clinician, relevant certification(s), and/or detailing any additional training that would satisfy the current regulatory standard) would help ensure that the data is appropriately informative and meets CMS' own needs for auditing and enforcement purposes. Additionally, we believe it is appropriate to collect this information at the initial determination level as well, if the initial determination resulted in a full or partial denial (i.e., if Element I-M is completed as "denied").

## IV. Public Reporting of Newly Collected Data

Finally, AMRPA wishes to reiterate its previous comments regarding the importance of making relevant MA data *publicly available* and easily accessible for all stakeholders. CMS should consider all opportunities to report the data collected from payers in an easily searchable, consistent, and coherent manner. As stated earlier, the current regulatory requirements for public transparency around prior authorization will only apply to plan-wide metrics; CMS should take the opportunity presented by this ICR to expand this to service-specific data. This should include plans' performance at the reconsideration level; understanding how frequently a plan reverses its initial decision on a request for authorization is an important metric for consumers to understand what to expect from their health plan choices.

Furthermore, the data should be aggregated at a central, CMS-supported, consumer-facing site, similar to the way consumers can use Care Compare in making decisions about health care providers. By stripping out identifying data elements (e.g., provider NPI, enrollee MBI, date of service, etc.), CMS should still easily be able to present the de-identified data and allow members of the public to review plans' own performance and consider whether any trends in

[13] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 Fed. Reg. 22,120, 22,220 (April 12, 2023).

their coverage determinations should impact beneficiaries' decision-making regarding their health plan options. Additionally, CMS should incorporate the data newly collected from plans into quality reporting programs, such as MA Organization Star Ratings, to ensure that payers are held accountable for their performance.

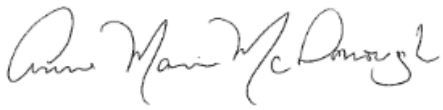
Finally, if and when CMS finalizes such public reporting, we urge the agency to consider incorporating plan-level performance at the Independent Review Entity (IRE) level of appeal as well. While de-identified information on IRE determinations is currently made available through the Medicare Part C & D Appeals Decision Search tool, this data is not linked to the MA organization initially offering the denial. Stakeholders including AMRPA have recently raised concerns that the IRE all too frequently may be "rubber stamping" denials by plans, with only 1.5% of IRF denials being overturned by the IRE between the beginning of 2020 and the first quarter of 2024.[14] Enhancing transparency into the results of this level of appeal, and tying performance back to individual MA organizations, would further bolster the ability of consumers to fully understand the potential impacts of their health care choices.

***

AMRPA appreciates the opportunity to comment on this ICR and we look forward to the finalized proposal. AMRPA and our members remain committed to working with CMS to ensure that the Medicare Advantage program and all payers maintain robust and appropriate access to medically necessary covered benefits for enrollees. If you have any questions regarding our comments, please contact Joe Nahra, AMRPA Director of Government Relations & Regulatory Policy, at (202) 207-1123 or by email at jnahra@amrpa.org.

Sincerely,

Chris Lee, MSPT, FACHE
Chair, AMRPA Board of Directors
Vice President and Chief Operations Officer – Madonna Rehabilitation Hospitals



Anne Marie McDonough, BSN, MPH, FACHE
Chair, AMRPA Denials Management Committee
Senior Director of Rehabilitation Medicine – Staten Island University Hospital Northwell Health

[14] Piper, Jermaine and Lane Koenig, "Medicare Advantage Prior Authorization Denials for Post-Acute Care Are Rarely Overturned," *KNG Health Consulting* (June 11, 2024). https://www.knghealth.com/medicare-advantage-prior-authorization-denials-for-post-acute-care-are-rarely-overturned/ (Finding that between January 1, 2020 and March 31, 2024, Medicare's IRE reviewed 48,938 appeals of IRF admission denials by MA organizations, and only overturned 764, while upholding more than 48,000 denials).

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

To whom it may concern,

Blue Cross Blue Shield of Michigan (BCBSM) appreciates the opportunity to submit comments regarding CMS' intention to collect service level data for initial determinations and appeals.

BCBSM is seeking clarification from CMS regarding the following elements of the proposal and appreciate the consideration in advance.

**Service Level Data for Initial Determinations**

- Plan is seeking clarification regarding whether Provider NPI(s) should be provided for data element D. It is not uncommon for organization determinations to contain information for several providers (i.e. rendering physician, referring physician, service location, etc.).
- Plan is seeking clarification if plans should report the primary code only for data elements F, G and H or if each detail line from the case should be reported separately.
- Plan is seeking clarification on what data should be provided for data elements F, G and H when codes are not available.
- Plan is seeking clarification regarding which zip codes should be provided for data element J as it is not uncommon for organization determinations to contain information for several providers (i.e. rendering physician, referring physician, service location, etc.).
- Plan is seeking clarification regarding which Date of Service should be provided for data element K as organization determinations may contain multiple dates of service, specific dates of service per requested service, date of service spans, and/or no dates of service provided.
- Plan is seeking clarification regarding which Provider Status(es) should be provided for data element L as it is not uncommon for organization determinations to include information for several providers (i.e. rendering physician, referring physician, service location, etc.).
- Plan is seeking clarification whether partially favorable, withdrawn, dismissals and/or re-opens should be included in data element M.
- Plan is seeking clarification whether the date populated in data element O is used to determine quarter inclusion or if the data populated in data element N should be used.
- Plan is seeking clarification regarding what data should be provided for data elements P and Q.
- Plan is seeking clarification if data element R applies only to claims as the plan assumes all Part C organization determinations would be considered prior authorizations.

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

**Service Level Data for All Appeals**

- Plan is seeking clarification as to what information the plan should provide for data element F.
- Plan is seeking clarification as to which reviewer(s) qualifications are required for data element G. Should qualifications include case coordinators, medical director or other qualifications?

**Additional Plan Comments & Feedback**

- Plan is seeking clarification whether organization determinations for supplemental benefits excluded from this reporting.
- Plan is seeking information from CMS regarding the timeline for finalizing these requirements.
- Plan is seeking clarification whether the initial determinations reporting section applies to both claims and authorizations.

BCBSM is appreciative of CMS's collection of plan feedback as well as the evaluation of our requests.

Sincerely,

Kaitlin Stretch
Manager, Regulatory Oversight & Compliance
Blue Cross Blue Shield of Michigan

# PUBLIC SUBMISSION

**As of:** 9/9/24, 1:15 PM
**Received:** September 06, 2024
**Status:** Draft
**Tracking No.** m0r-452i-tl3j
**Comments Due:** October 08, 2024
**Submission Type:** API

**Docket:** CMS-2024-0276
Service Level Data Collection for Initial Determinations and Appeals (CMS-10905)

**Comment On:** CMS-2024-0276-0001
Service Level Data Collection for Initial Determinations and Appeals (CMS-10905)

**Document:** CMS-2024-0276-DRAFT-0002
Comment on CMS-2024-0276-0001

## Submitter Information

**Email:** tuan.nguyen@bcbsma.com
**Organization:** Blue Cross Blue Shield of Massachusetts

## General Comment

For Section I Service Level Data for all initial Determinations, can you please clarify Element U, what a voluntary pre-service request is.

For Section II Service Level Data for all Appeals, can you please clarify what data is needed for Data Element G, Reviewer Qualification.

| Section/Title | Commentor | Functional Area | Comment(s) |
|---|---|---|---|
| Section I / Service Level Data for all Initial Determinations | Lisa Johnson | Compliance | Would Element K be optional (e.g. required for Claims, not required for PA)? |
| Section I / Service Level Data for all Initial Determinations | Lisa Johnson | Compliance | For Element U, how does CMS define "voluntary pre-service request?" |
| Section II / Service Level Data for all Appeals | Lisa Johnson | Compliance | For Element F, would CMS provide codes to utilize or will this field be freeform? |
| Section II / Service Level Data for all Appeals | Lisa Johnson | Compliance | Will CMS consider adding appeal number as well to this section for better plan tracking/validation? |
| Section II / Service Level Data for all Appeals | Lisa Johnson | Compliance | For Element G, will CMS provide codes to utilize or will this field be freeform? |
| Section I. Service Level Data for all Initial Determinations | Christie Kosiak | Clinical Operations | Item F wants CPT/HCPS codes, some of our auths are entered as service groups. Ie. Colonoscopies are 0052 vs the cpt code - would this suffice otherwise we have system limitations |
| Section I. Service Level Data for all Initial Determinations | Christie Kosiak | Clinical Operations | Item Q is that specific to internal policies like Centene or Fidelis vs MCG or LCD/NCD? |
| Section I. Service Level Data for all Initial Determinations | Christie Kosiak | Clinical Operations | Item T and U not sure we have system capability to build logic on whether or not a PA was required and pull to a report with a response. We only build auths that require auth so likely we could standardize it as Y across the board for UM |
| Section II. Service Level Data for all Appeals | Christie Kosiak | Clinical Operations | Item G - system limitations for building logic specific to MD credentials. |

Center for Medicare Advocacy
MedicareAdvocacy.org

October 8, 2024

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control No.: 0938-New
Room C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

**Submitted electronically to:** https://www.regulations.gov

**Re: File Code CMS-10905; OMB Control No: 0938-New; Federal Register, Volume 89, No. 154 (August 9, 2024) Agency Information Collection Activities; Service Level Data Collection for Initial Determinations and Appeals**

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

CMS notes: "The Part C and D Reporting Requirements, as set forth in §§ 422.516(a) and 423.514(a), provide CMS with the ability to collect more granular data related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions. This includes collecting more timely data with greater frequency or closer in real-time."

We write in strong support of this proposed collection notice and assert that it is both necessary and useful for proper performance of CMS' functions. We strongly agree that the proposed data elements listed in the Technical Specifications document would provide key data to CMS on the utilization of benefits, allow it to enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits.

As an organization that provides direct services to Medicare beneficiaries, we know first-hand the struggles that many Medicare Advantage enrollees endure in trying to obtain medically necessary care from their plans. We also know that information about how plans adjudicate requests for coverage, and the results of plan decisions, is not readily available and accessible to the public. Collecting this information is critical in order to appropriately monitor plan compliance and hold them accountable for their performance.

In the Supporting Statement – Part A, CMS states:

> The proposed data elements listed in the Technical Specifications document in this proposed PRA would provide key data to CMS on the utilization of benefits, enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits. We particularly solicit input on how health plans can most efficiently provide information to CMS on their decision rationales for initial determinations and appeals. Recognizing this information is already required to be provided in beneficiary correspondence, CMS is interested in how best to also be a recipient of this information.

We strongly support CMS' collection of this data from plans, but take issue with CMS' assumption that while such "information is already required to be provided in beneficiary correspondence" that such information is, in fact, regularly provided to beneficiaries. In our experience, MA plans routinely fail to meet their existing obligations to provide adequate notice to beneficiaries concerning the rationale for denials of care.[1]

Further, we urge CMS to make this collected data publicly available on the www.medicare.gov website in a manner that is easily accessible and utilized by the public, including Medicare beneficiaries, in order to make more informed decisions about their coverage.

**Conclusion**

Thank you for the opportunity to provide these comments. For additional information, please contact David Lipschutz DLipschutz@MedicareAdvocacy.org at (202)293-5760.

David Lipschutz
Co-Director/Attorney

[1] See, e.g., Center for Medicare Advocacy Comments on Proposed 2024 Part C & D Rule (Feb. 13, 2024), available at: https://medicareadvocacy.org/wp-content/uploads/2023/02/C-and-D-Comments-CY-2024.pdf.

**CMS-10905: Service Level Data Collection for Initial Determinations and Appeals** – Cigna Healthcare Comments, 9/30/2024

| Section | CMS Summary of Changes | Comments |
|---|---|---|
| Report Section I:<br><br>Service Level Data for all Initial Determinations | Data Element P:<br><br>Decision Rationale | Please provide guidance about how to report the Decision Rationale information in Data Element P. Is the Decision Rationale a high-level synopsis of the decision? |
| Report Section I:<br><br>Service Level Data for all Initial Determinations | Data Element T:<br><br>If element R is yes, was PA request required? | When Data Element F contains service codes that both 'require and do not require' a PA, should Data Element T be populated with "Yes"?<br><br>• Data Element F: Requested service codes (CPT/HCPCS)<br>• Data Element R: Was PA requested?<br>• Data Element T: If element R is yes, was PA request required? |
| Report Section I:<br><br>Service Level Data for all Initial Determinations | Data Element U:<br><br>If element R is yes, was a voluntary pre-service request received? | Please define "voluntary pre-service request received." Is this when the Plan does not require a PA? |

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| State/Local Health department staff | Form 1 Medical Tourism Case Intake Form (Part B-Medical Chart Abstraction). | 50 | 15 | 5/60 | 63 |
| Ill persons who have experienced an adverse health outcome related to medical tourism. | Form 1 Medical Tourism Case Intake Form (Part A-Interviews). | 750 | 1 | 10/60 | 125 |
| Ill persons who have experienced an adverse health outcome related to medical tourism. | Form 2 Medical Tourism Enhanced Surveillance Form. | 500 | 1 | 30/60 | 250 |
| Total | | | | | 438 |

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.*

[FR Doc. 2024–17764 Filed 8–8–24; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10147 and CMS–10905]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by October 8, 2024.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:**

### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10147 Medicare Drug Coverage and Your Rights

CMS–10905 Service Level Data Collection for Initial Determinations and Appeals

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### Information Collections

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Medicare Drug Coverage and Your Rights; *Use:* Section 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) require that Part D plan sponsors' network pharmacies provide Part D enrollees with a printed copy of our standardized pharmacy notice ''Medicare Drug Coverage and Your Rights'' (hereafter, ''notice'') if an enrollee's prescription cannot be filled.

The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. The notice reminds enrollees about certain rights

and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered. Through delivery of this standardized notice, a Part D plan sponsor's network pharmacies are in the best position to inform enrollees at point of sale about how to contact their Part D plan if the prescription cannot be filled. *Form Number:* CMS–10147 (OMB control number: 0938–0975); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not for-profits; *Number of Respondents:* 72,900; *Number of Responses:* 55,215,940; *Total Annual Hours:* 919,898. (For policy questions regarding this collection contact Sabrina Edmonston at 410–786–3209 or *Sabrina.edmonston@cms.hhs.gov*).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Service Level Data Collection for Initial Determinations and Appeals; *Use:* The Part C and D Reporting Requirements, as set forth in §§ 422.516(a) and 423.514(a), provide CMS with the ability to collect more granular data related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions. This includes collecting more timely data with greater frequency or closer in real-time. The proposed data elements listed in the Technical Specifications document in this proposed PRA would provide key data to CMS on the utilization of benefits, enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits.

CMS staff will use this information to monitor health plans and to hold them accountable for their performance. CMS users include group managers, division managers, branch managers, account managers, and researchers. Health plans can use this information to measure and benchmark their performance. CMS receives inquiries from the industry and other interested stakeholders about beneficiary access to the items, services, and drugs, including service level data for initial determinations and appeals, and other factors pertaining to use of government funds, as well the performance of MA plans. *Form Number:* CMS–10905 (OMB control number: 0938-New); *Frequency:* Quarterly; *Affected Public:* Private Sector, Business or other for-profits, Not for-profits and Federal Government State, Local; *Number of Respondents:* 728; *Number of Responses:* 2,912; *Total Annual Hours:* 728. (For policy questions regarding this collection contact Sabrina Edmonston at 410–786–3209 or *sabrina.edmonston@cms.hhs.gov*).

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2024–17773 Filed 8–8–24; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Child Abuse and Neglect Background Checks for Child Care and Early Education Project (New Collection)

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF) is proposing an information collection activity for the Child Abuse and Neglect Background Checks for Child Care and Early Education (CAN Checks for CCEE) Project. The goal of the project is to better understand how states and territories use findings from CAN registry background checks, as required by the Child Care and Development Block Grant Act of 2014 (CCDBG), to make child care employment eligibility determinations. The study will also be used to understand state and territory variation, facilitators, and challenges in implementing CAN registry background checks; and explore any resulting within- or across-state/territory equity implications.

**DATES:** *Comments due within 30 days of publication. The Office of Management and Budget (*OMB) must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* All emailed requests should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The proposed information collections for the CAN Checks for CCEE Project is designed to explore how states and territories implement CAN registry background checks for child care employment eligibility decisions. While the CCDBG Act of 2014 clearly describes procedures and exclusionary criteria pertaining to the use of criminal and sexual offender registry background checks to inform child care employment eligibility decisions, requirements for the use of CAN registry background checks are less clear. The findings will be of interest to ACF, and, in particular, to OPRE and the Office of Child Care, who are interested in the effective and equitable implementation of CAN registry background checks for prospective and current child care staff. Findings will also be of interest to Child Care and Development Fund (CCDF) state/territory lead agencies that oversee the CCDF program in their states/territories and the state/territory offices that oversee early care and education. The results of this study also have implications for child care programs and staff. Further, given the U.S. Congress' interest in prior exploratory work on this topic, it may also be informative to federal lawmakers.

CCDF lead agency staff that participate in this information collection will be asked to complete a voluntary, one-time web-based survey. The survey will focus on the practices and policies related both to in-state/territory and interstate CAN registry checks, including what data they request and receive, as well as how they use it in making child care employment eligibility decisions.

*Respondents:* Each state, territory, and the District of Columbia will be invited to complete one web-based survey. Given that each agency may have multiple staff members with relevant knowledge of different survey topics and no one staff member may possess all of the knowledge to complete the survey, CCDF Lead Agencies may have multiple staff members work together to complete the survey. For burden estimates, we are assuming up to 3 respondents may work on the survey

4120-01-U-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**[Document Identifiers: CMS-10147 and CMS-10905]**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA web site by copying and pasting the following web address into your web browser: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

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CMS-10905 Service Level Data Collection for Initial Determinations and Appeals

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reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

*Information Collections*

1. *Type of Information Collection Request*: Revision of a currently approved information collection; *Title of Information Collection*: Medicare Drug Coverage and Your Rights; *Use*: Section 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) require that Part D plan sponsors' network pharmacies provide Part D enrollees with a printed copy of our standardized pharmacy notice "Medicare Drug Coverage and Your Rights" (hereafter, "notice") if an enrollee's prescription cannot be filled.

The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. The notice reminds enrollees about certain rights and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered. Through delivery of this standardized notice, a Part D plan sponsor's network pharmacies are in the best position to inform enrollees at point of sale about how to contact their Part D plan if the prescription cannot be filled. *Form Number*: CMS-10147 (OMB control number: 0938-0975); *Frequency:* Yearly; *Affected Public*: Private Sector, Business or other for-profits, Not for-profits; *Number of Respondents*: 72,900; *Number of Responses:* 55,215,940; *Total Annual Hours:* 919,898. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209 or Sabrina.edmonston@cms.hhs.gov).

2. *Type of Information Collection Request*: New collection (Request for a new OMB control number); *Title of Information Collection*: Service Level Data Collection for Initial

Determinations and Appeals; *Use*: The Part C and D Reporting Requirements, as set forth in §§ 422.516(a) and 423.514(a), provide CMS with the ability to collect more granular data related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions. This includes collecting more timely data with greater frequency or closer in real-time. The proposed data elements listed in the Technical Specifications document in this proposed PRA would provide key data to CMS on the utilization of benefits, enhance audit activities to ensure plans are operating in accordance with CMS guidelines, and ensure appropriate access to covered services and benefits.

CMS staff will use this information to monitor health plans and to hold them accountable for their performance. CMS users include group managers, division managers, branch managers, account managers, and researchers. Health plans can use this information to measure and benchmark their performance. CMS receives inquiries from the industry and other interested stakeholders about beneficiary access to the items, services, and drugs, including service level data for initial determinations and appeals, and other factors pertaining to use of government funds, as well the performance of MA plans. *Form Number*: CMS-10905 (OMB control number: 0938-New); *Frequency:* Quarterly; *Affected Public*: Private Sector, Business or other for-profits, Not for-profits and Federal Government State, Local; *Number of Respondents*: 728; *Number of Responses:* 2,912; *Total Annual Hours:* 728. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209 or sabrina.edmonston@cms.hhs.gov).

**William N. Parham, III**

*Director,*

*Division of Information Collections and Regulatory Impacts,*

*Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2024-17773 Filed: 8/8/2024 8:45 am; Publication Date: 8/9/2024]

October 8, 2024

ELECTRONIC SUBMISSION VIA www.regulations.gov

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

**RE: CPR Comments on Service Level Data Collection for Medicare Advantage Plans (CMS-10905)(OMB Control Number: 0938-New)**

Dear Administrator Brooks-LaSure:

The undersigned members of the Coalition to Preserve Rehabilitation ("CPR") appreciate the opportunity to submit these comments to the Centers for Medicare and Medicaid Services ("CMS") in response to its intent to collect service level data on Medicare Advantage ("MA") determinations and appeals.[1] CPR members commend CMS for taking the necessary steps to monitor MA plan compliance with Medicare requirements and enhance transparency in the MA program. We firmly believe that the collection of more detailed service line data is fundamental to the program's overall success and the ability of CMS to ensure that MA beneficiaries receive the vital services to which they are entitled under the Medicare program. We offer the following recommendations to assist MA plans in identifying areas of improvement and ensure that MA plans are held accountable for misusing—or even abusing—utilization management tools.

CPR is a coalition of national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain their maximum level of health and independent function. CPR is comprised of organizations that represent patients – as well as the providers who serve them – who are frequently inappropriately denied access to rehabilitative care in a variety of settings, including inpatient rehabilitation hospitals and units.

## Benefits of Collecting Setting-Specific Data

CPR fully supports the collection of service line data under MA plans. We believe that the collection of this more granular level of data will not only assist in painting a more

[1] Agency Information Collection Activities: Proposed Collection; Comment Request, CMS-10905- Service Level Data Collection for Initial Determinations and Appeals, 89 Fed. Reg. 65,359 (Aug. 9, 2024).

comprehensive picture of how the MA program is operating, but also lead to more targeted improvements, informed decision-making, and equitable care delivery, ultimately enhancing the overall quality and efficiency of the program in the future. More specifically, the collection of setting-specific data would enable a granular assessment of performance across different care settings, particularly in outpatient rehabilitation centers and the post-acute care settings, which include inpatient rehabilitation facilities ("IRFs"), skilled nursing facilities ("SNFs"), home health agencies, and hospice care. CPR believes that this level of specificity would allow for more precise measurement of coverage denials and appeals within each service line, leading to more targeted quality improvement initiatives to ensure that enrollees are receiving the medically necessary care they need.

The collection of more detailed service line data would greatly assist CMS in revealing disparities in access to and quality of care among different settings. By identifying gaps in service delivery and outcomes across service lines, MA plans would thereby be able to develop targeted interventions, instead of one-size-fits all approaches, to address these disparities and improve equity in healthcare access and quality. CPR believes that service line data is also critical for strategic planning and policy development. The collection of setting-specific data would provide insights into service utilization trends, identify emerging needs, and support the creation of policies that address specific challenges within different service lines. This data-driven approach would ensure that policies are relevant and effective in improving access to quality care across various specialties.

Comprehensive service line data would also enhance transparency and accountability by providing a clear view of how different service lines perform. This transparency would help CMS better understand the quality of care being provided in each setting, thereby holding MA plans more accountable for their performance. Accurate service line data would also support effective resource allocation by identifying which areas require more support or investment. This information would help MA plans allocate resources efficiently, ensuring that high-need service lines receive appropriate funding and support to enhance care delivery and patient outcomes.

**Prior Authorization**

CPR commends CMS for its recent regulatory action to reign in the overreaches of MA organizations that employ utilization management tools that inappropriately delay and deny care to beneficiaries, such as prior authorization. The Contract Year 2024 and 2025 MA final rules established guardrails for MA plans to prevent beneficiaries from severe barriers to access to post-acute care, whether due to restrictive coverage policies, improper use of prior authorization, or other utilization management techniques and administrative burdens.[2] The recently finalized

[2] "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." *Federal Register* 88:70 (April 12. 2023) at 22120 et seq.; "Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." *Federal Register* 89:79 (April 23, 2024) at 30448.

Advancing Interoperability and Improving Prior Authorization Processes rule builds on those new patient protections and addresses key issues with prior authorization including requiring written reasons for denials, shortening timeframes for decisions of appeals, and requiring greater transparency from payers.[3]

Prior authorization continues to be a serious impediment to care for beneficiaries with disabilities and individuals seeking medical rehabilitative care. CPR members, both beneficiaries and providers, continue to experience problems with prior authorization denials and hurdles in MA plans despite the new patient protections that took effect January 1, 2024. CPR encourages CMS to continue to enforce the new regulations and audit plans to ensure that beneficiaries are able to see the full impact of these new regulations in practice.

In addition to enforcement by CMS, CPR supports increased transparency from MA plans about their use of prior authorization and metrics on denials and approvals. As established in the Advancing Interoperability and Improving Prior Authorization Processes final rule, beginning in 2026, MA plans will be required to publicly report certain prior authorization metrics annually by posting them on the plan website. CMS also established in the Contract 2025 final rule that MA plans will be required to conduct an annual health equity analysis of the use of prior authorization and its impact on enrollees with one or more social risk factors at the plan level.

CPR continues to support these new transparency regulations and we strongly encourage CMS to require the collection of service line level data to help assess both inpatient hospital rehabilitation and Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") from MA plans. More granular data for SNFs, home health agencies, physician offices, outpatient therapy services, and other sites of care would also be helpful. Instead of receiving and analyzing MA data in the aggregate, CMS would be able to view a much more site-specific picture resulting in their ability to better compare multiple payers' prior authorization metrics at the service line level. Only with this more granular level of specificity will CMS be able to assess which services are routinely denied, appealed, and overturned in favor of patients and providers, leading to reforms to accelerate access to appropriate, timely, and necessary care.

CPR is concerned that prior authorization denials in several post-acute care settings are more common than in other settings, as has been recognized in a 2022 OIG report, and that these disparities in approvals are largely concealed with the current aggregated data reporting requirement.[4] Post-acute care is essential for people with disabilities, illnesses, injuries, and chronic conditions to receive medical rehabilitation services, and the well-documented denials of care for this at-risk population demands further examination. In addition to provider setting data,

[3] "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program." *Federal Register* 89:27 (February 8, 2024) at 8758 et seq.

[4] U.S. Department of Health and Human Services, Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care; Report (OEI-09-18-00260) (Apr. 2022).

CMS could improve health equity for beneficiaries by requiring analysis at the level of items and services, particularly examining beneficiary access to DMEPOS instead of aggregating for all items and services. Moreover, requesting data that extends back over several contract years for these areas of care that are particularly needed by people with disabilities will further illuminate longstanding discriminatory patterns of care denials. Only with this level of specificity will CMS be able to assess which items are routinely denied, appealed, and overturned in favor of patients and providers.

**Reviewer Qualifications**

CPR advocates for the collection of data on reviewer qualifications when making an initial medical necessity determination. Under current regulations, if a MA plan intends to issue a partial or fully adverse medical necessity decision based on the initial review, the determination must be reviewed by a "physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision."[5] Accordingly, CPR urges CMS to mandate the reporting of this required and specific clinical background information to ensure that Medicare Advantage plans are hiring clinically appropriate health care professionals to do this important work.

**Network Adequacy**

In recent years, CMS has updated network adequacy standards for MA plans, largely focused on behavioral health. In previous years, CMS has also revised the time and distance standards, as well as the list of provider and facility specialty types subject to network adequacy reviews. CMS, however, does not currently include post-acute rehabilitation programs, including IRFs, comprehensive outpatient rehabilitation facilities ("CORFs"), and long-term acute care hospitals ("LTCHs") in the list of facility specialty types evaluated during these reviews.

These are critical settings of care for patients in need of rehabilitation services and devices, and their omission in network adequacy reviews is glaring. This is underscored by the fact that CMS includes IRFs, CORFs, and LTCHs as a covered benefit under traditional Medicare, and hundreds of thousands of Medicare enrollees benefit from treatment offered by these providers on an annual basis. CPR strongly urges CMS to include IRFs, CORFs, and LTCHs as part of the agency's network adequacy review process for MA plans and to provide that information to MA enrollees in an easily accessible format.

In addition to requiring MA plans to offer access to post-acute rehabilitation and reviewing the plans for adequate networks, CPR believes that MA plans should provide more information to beneficiaries about their provider networks through provider directories available on publicly accessible websites. Provider networks are a critical component of Medicare Advantage plans, directly impacting beneficiaries' access to care. Insufficient networks can limit provider choice and accessibility, particularly in rural and underserved areas. However, there is insufficient publicly available data on the composition and adequacy of provider networks within MA plans.

[5] 42 C.F.R. § 422.566(d)

Enhanced transparency in provider network data will enable beneficiaries to make informed choices regarding their healthcare plans and ensure MA plans maintain networks that meet the healthcare needs of their enrollees. CPR recommends that CMS enhance transparency for beneficiaries by requiring MA plans to report data on geographic distribution and network sufficiency of all critical services, including post-acute rehabilitation, to meet the needs of enrollees, particularly in rural and underserved areas. It would also be helpful to beneficiaries considering the choice between Traditional Medicare or an MA plan to see comparative metrics on provider access in their geographic area. This geographic data is increasingly important as healthcare providers and hospitals drop MA plans due to excessive prior authorization denials, low payment rates, and for other reasons.

**********

We greatly appreciate your consideration of our comments. Should you have any further questions regarding this information, please contact Peter Thomas and Michael Barnett, CPR co-coordinators, by e-mailing Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

**The Undersigned Members of the Coalition to Preserve Rehabilitation**

ACCSES
ADVION (formerly National Association for the Support of Long Term Care)
ALS Association
American Academy of Physical Medicine & Rehabilitation
American Association on Health and Disability
American Music Therapy Association
American Physical Therapy Association
American Speech-Language-Hearing Association
American Spinal Injury Association (ASIA)
American Therapeutic Recreation Association
Amputee Coalition
Association of Academic Physiatrists
Association of Rehabilitation Nurses
***Brain Injury Association of America****
Clinician Task Force
Disability Rights Education and Defense Fund (DREDF)
Epilepsy Foundation of America
***Falling Forward Foundation****
Lakeshore Foundation
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
National Association of Rehabilitation Providers and Agencies
National Association of Social Workers (NASW)

National Disability Rights Network (NDRN)
RESNA
Spina Bifida Association

**** Indicates CPR Steering Committee Member***

1275 Pennsylvania Ave. NW
Suite 700
Washington, DC 20009

October 8, 2024

William N. Parham, III
Director
Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevad
Baltimore, MD 21244-1850

**RE: Service Level Data Collection for Initial Determinations and Appeals (CMS-10905)**

Dear Director Parham:

CVS Health appreciates the opportunity to comment on the Department of Health and Human Services (Department or HHS), Centers for Medicare & Medicaid Services' (CMS) August 9, 2024 proposal to gather more granular data on plan activities adjudicating coverage requests and plan procedures for making service utilization decisions.

We support CMS' efforts to ensure all beneficiaries have equitable access to Medicare program offerings and recognize the interest in collecting more data to understand initial determinations and appeals. While we agree with CMS' proposal to increase transparency, our main concern centers on a proposed implementation timeline that does not account for the significant investment of time and resources necessary to ensure accurate and valid data. Capturing several of the proposed elements would require extensive manual entry and validation.

We recommend CMS require the first quarterly reporting in 2026 using 2025 data, rather than the proposed reporting start in 2025 based on 2024 data. We strive to provide accurate and timely data in a manner that does not in any way obstruct the ability to provide timely, cost-effective care to beneficiaries. This will ensure sufficient time to prospectively update processes based on the data elements provided by CMS, reconfigure internal systems, and train staff and personnel dedicated to quarterly reporting. Most importantly, this would allow plans to thoroughly test and validate collected data to ensure the accuracy of what is being reported to CMS.

As part of our comments, we also ask CMS to provide clarification on the following data elements to assist with our implementation of this data collection:

1. Please confirm our understanding of the definitions and relationships between:

- Data Element ID R, "Was Prior Authorization (PA) requested"
- Data Element ID T, "If element R is yes, was PA request required?"
- Data Element ID U, "If element R is yes, was a voluntary pre-service request received?"

Our understanding of the above data elements is the following:

- When a PA is requested by a member, member's representative, or their provider, Data Element R is yes.
- When a plan makes an OD decision in the absence of a PA request from the member, member's representative, or provider, Data Element R is no.
    - Example: MAPD plan has medical claims data that demonstrates drug should pay under the Part B benefit rather than the Part D benefit, so they authorize the drug under the Part B benefit going forward.
- When a plan requires a PA as a condition of payment, Data Element ID T is yes. It would also be yes when reviewing a request to waive step therapy, to exceed a plan imposed quantity limit, or to waive any other UM requirement.
    - Data Element T is no when either (a) the plan makes an OD decision for a drug, item, or service that is not subject to a UM restriction, or (b) the member, member's representative, or provider requests an OD even though the plan does not require a PA.
- When a PA was requested by a member, their provider, or their prescriber (Data Element R= yes), but it was not required (Data Element T= N), Data element U would be 'Yes" because this represents a "voluntary pre-service request."

2. Data Element ID D: We recommend CMS assist in ensuring the collection of this data element by requiring providers to submit their NPI on requests and appeals submitted to plans.

3. Data Elements F,G,H: Certain requests may include multiple services and/or service codes, especially where a provider is encouraged to submit one request for a treatment plan. We ask CMS to consider how to best collect data where multiple services may be included on one request and result in a partial approval, and/or appeal, or denial.

4. Data Element S: If prior authorization is requested and the answer is "yes" under Data Element R, CMS requests the organization determination (OD) number for prior authorization (claims only). We ask CMS to clarify if this data element is only seeking determinations related to claims and/or preservice ODs.

5. Section II, Data Element G: We ask CMS to provide additional detail on how "Reviewer qualifications" must be captured. Is CMS seeking information on the reviewer's professional credentials (e.g., MD, DO)?

Thank you for considering our requests. We appreciate CMS' willingness to continue engaging with the industry. We are focused on ensuring any data collection is efficient and results in the reporting of accurate data to CMS. Please do not hesitate to contact us with any questions about these comments.

Sincerely,

Melissa Schulman
Senior Vice President
Government & Public Affairs
CVS Health

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William N. Parham, III
Director
Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services

Re: Document Identifier CMS-10905; Agency Information Collection Activities; Proposed Collection; Comment Request; Service Level Data Collection for Initial Determinations and Appeals

Dear Director Parham:

On behalf of the more than 206 hospitals and health systems across New York, New Jersey, Connecticut, Pennsylvania and Rhode Island that make up the acute care membership of the Greater New York Hospital Association (GNYHA), thank you for the opportunity to comment on the proposed Medicare Advantage (MA) Plan Service Level Data Collection for Initial Determinations and Appeals (the Service Level Data Collection) published by the Centers for Medicare & Medicaid Services (CMS) on August 9, 2024 (89 FR 65359).

Over the past several years, GNYHA has provided extensive feedback to CMS regarding our member hospital experiences and frustrations with MA plans, particularly with utilization management (UM) practices. We also responded to CMS's January 2024 Request for Information on MA Data, emphasizing the need for meaningful data collection to inform regulatory oversight of MA plans and offering suggestions for data collection principles and measures. We are encouraged that CMS is now preparing to implement enhanced data collection activities and is seeking feedback on the tools for doing so.

We understand this Service Level Data Collection to be one of several proposals CMS is developing to establish robust reporting requirements for MA plans. GNYHA will separately provide extensive feedback on the proposed MA UM Annual Data Submission and Audit Protocol Data Request. The Service Level Data Collection, UM Annual Data Submission, and Audit Protocol Data Request are all important for creating a meaningful data transparency infrastructure.

## The Context

We were extremely pleased when CMS finalized comprehensive UM program guardrails in the calendar year (CY) 2024 final rule. Among other requirements, the CY 2024 final rule set forth important limitations on when and how MA plans can apply prior authorization (PA) and when using internal coverage criteria to establish medical necessity is permissible. CMS also underscored the core principle that MA plans must cover the same benefits as fee-for-service (FFS) Medicare and follow FFS coverage criteria and guidelines.

However, as expressed in our previous comments, GNYHA members report that certain MA plans continue to interpret and implement UM requirements in ways that seem inconsistent with the regulatory language and intent. It is imperative that CMS have insight into how its regulations are being implemented and the associated impact on MA beneficiaries and providers.

Based on GNYHA member feedback that certain MA plans continue to use internal coverage criteria and concerns about both the scope of use (i.e., is use limited to services for which Medicare coverage criteria are not fully established) and substance (i.e., are the internal criteria based on widely used treatment guidelines and clinical literature and do they meet the public accessibility requirements) of these tools, we have urged that MA plans be required to report those procedures or services for which they apply internal criteria and specify the criteria used and whether each criteria meets the CY 2024 final rule requirements. We have also recommended that more targeted outcomes data be collected for the two-midnight benchmark and inpatient stays.

While the UM Audit Protocol Data Request appears to more directly address MA plan compliance with the CY 2024 final rule, including use of internal coverage criteria, we understand this Service Level Data Collection would more broadly assess coverage determinations.

## The Proposal

CMS proposes data collection elements with the goals of providing key data to CMS on benefit utilization, enhancing audit activities to ensure plans are operating in accordance with CMS guidelines and ensuring appropriate access to covered services and benefits. CMS states it will use the collected data to monitor MA plans and suggests that plans can use the data to evaluate their own activity.

MA plans would be required to report on each received request for coverage, detailing the specific provider, service, patient, outcome, and decision rationale. The proposed data collection would also track the date of coverage request and the date of decision, whether internal plan criteria were applied, and whether PA was requested and required. Appeals of initial determinations, and the time from appeal request to appeal decision would be reported. Additionally, MA plans would identify reviewer qualifications on appeal.

In general, the proposal is a helpful step toward transparency, particularly when viewed as one piece of a larger data collection infrastructure. The proposed data collection focuses on several measures that are important for understanding how MA plan service utilization decisions may impact access to care and coverage and whether MA enrollees are receiving the same benefits as FFS beneficiaries. We highlight these data points below and also suggest where CMS could expand data collection to further illuminate the nuances in PA and service utilization determinations that can create disparities in coverage.

***Services, Settings, and Provider Types:*** We support collection of initial determinations at the provider and service code and category level (Proposed Data Elements I.D, F, G, and H). Collecting place of service codes (Proposed Data Element I.V) is also useful, as identifying coverage determinations by broader provider categories can more fully illuminate the impacts of site of service and other internal plan coverage rules.

***Decision Timeliness***: Decision timeliness is critical to understanding the interplay between MA plan review processes and coverage delays. We strongly support collecting receipt and decision dates for both initial determinations and appeals (Proposed Data Elements I.N and O, and II.C and D). The proposal to collect information linking reported appeal data elements to the initial decision (Proposed Data Element II.A) is also fundamentally important, as it allows calculation of the time from initial determination request to appeal decision date. The time elapsed between an initial PA request and decision is irrelevant if the initial decision is a denial and the patient is not able to access care until a final determination is rendered on appeal.

For clarity, we suggest CMS provide guidance on how to calculate "date request received" (Proposed Data Element I.N) for services that do not require or did not receive PA (e.g., is this always the date of claim receipt).

MA plans should also report on decisions that are pending or unresolved. Pended claims can often languish and would not necessarily be captured under the current proposal.

***Decision Outcomes:*** In addition to reporting whether a service was approved or denied, MA plans should further specify when a service was partially approved and/or approved with a modification. Our member hospitals struggle with MA plan downgrading, and there is insufficient data on the scope of this practice. Downgrading is particularly prevalent for inpatients who are ultimately covered only at an outpatient level, but the practice is also reported in many other situations and should be more fully understood.

***Decision Rationale***: We commend CMS's focus on decision rationale transparency. GNYHA members report that MA plan denial notices are often inadequate and do not contain sufficient information to allow providers to craft meaningful appeals. Rationales are described as conclusory and without citation to MA plan-specific policy, benefit design, clinical guideline, etc. It is thus critical that CMS have access to decision rationale, and we urge CMS to continue exploring optimal mechanisms for doing so.

Further, it is unclear from the proposal whether the "decision rationale" data element (Proposed Data Elements I.P and II.F) is currently envisioned as an open text field. To facilitate analysis and identification of trends, we suggest CMS collect denial reason by category—administrative or clinical—in addition to any decision rationale detail or narrative. Open text risks each MA plan using different terminology or descriptors for the same rationale, which makes aggregating and analyzing data challenging.

- Administrative denials should include reasons such as no PA on file, failure to notify, late claims submission, and other similar denials for not adhering to procedural requirements
    - Duplicate claim, ineligibility, and "not covered benefit" denials should not be included as administrative denials. CMS could consider adding a third category of "other" for such denials.
- Clinical denials should include medical necessity, level of care, fail first, etc.

***Reviewer Qualifications***: We strongly support the proposal to collect information on reviewer qualifications for appeals (Proposed Data Element II.G). However, reviewer qualifications should also be collected for initial determinations, given that initial medical necessity denials must be made by a provider with expertise in the relevant field of medicine. Having this information reported for both initial

determinations and appeals will illuminate outcome discrepancies based on reviewer expertise and allow a more robust data set for assessing the impact of reviewer qualifications on denials.

***Use of Internal Coverage Criteria***: As more fully discussed above, in GNYHA members' experience, MA plans are continuing to apply internal coverage criteria in ways that seem prohibited by the CY 2024 final rule. In the interest of transparency, we strongly support CMS's proposal to require MA plans to report whether internal plan criteria were applied (Proposed Data Element I.Q.). This question should be reported for both initial determinations and appeals. However, we query the usefulness of a Y/N response indicating whether criteria were used but that does not alone facilitate a deeper analysis and understanding of when and how plans are applying internal criteria and the implications for coverage denials and delays. We know that CMS is proposing to collect more robust detail on MA plan use of internal criteria under the MA Audit Protocol, and we urge CMS to consider all available data when assessing MA plan internal criteria use.

Thank you for the opportunity to comment on this proposed data collection. We look forward to working with you to improve the MA program for providers and beneficiaries. Please contact me with any questions.

Sincerely,

Emily Leish
Senior Vice President, Health Finance and Managed Care

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October 8, 2024

**SUBMITTED ELECTRONICALLY VIA WWW.REGULATIONS.GOV**

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

**RE: Healthcare Legal Solutions' Comments on Service Level Data Collection for Initial Determinations and Appeals (CMS-10905) (OMB Control Number: 0938-New)**

Dear Administrator Brooks-LaSure:

Healthcare Legal Solutions ("HLS") appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services' ("CMS's") intent to collect service level data on Medicare Advantage ("MA") determinations and appeals.[1] We appreciate CMS's efforts to enhance transparency in the MA program and monitor compliance with federal directives governing MA plans' review of claims. We believe that the collection of detailed service level data would greatly assist CMS in determine whether MA plans are inappropriately denying claims and arbitrarily preventing enrollees from receiving the medically necessary care they need. We respectfully offer the following recommendations to help MA plans identify areas of improvement and ensure that MA plans are held accountable for abusing utilization management tools.

HLS is a law firm that appeals and recovers complex third-party payer denials for our hospital clients. HLS prides itself on providing high-quality legal/denials recovery services, and we have a long track record of successfully representing hospitals in administrative appeals challenging claim denials by public and private payers, including, but not limited to, MA plans. We have successfully represented acute care, chronic, children's, and rehabilitation hospitals in administrative appeals that involve standard and complex claims.

Our hospital clients have repeatedly expressed concerns regarding MA plans inappropriately denying requests for prior authorization and payments to providers. HLS's attorneys and other professionals have assisted hospitals in appealing these denials.

[1] Agency Information Collection Activities: Proposed Collection; Comment Request, CMS-10905- Service Level Data Collection for Initial Determinations and Appeals, 89 Fed. Reg. 65,359 (Aug. 9, 2024).

HLS applauds the agency for the increased regulatory attention on the MA program in an effort to prevent and correct egregious overreaches by MA plans. We strongly supported the recent final rules that prevent MA plans from denying coverage or payment based on medical necessity if a patient requested and received a pre-service approval, establish the appropriate use of prior authorization, require a minimum of 90-day transition period for an enrollee undergoing a treatment switching to a new MA plan, and prohibit plans from denying services based on internal criteria that go beyond Traditional Medicare coverage rules unless certain circumstances are met. However, despite these regulations, providers are still reporting inappropriate denials.

We believe that greater oversight is needed of MA plans. In addition, we urge CMS to move forward with the collection of comprehensive service level data from MA plans to help identify service utilization trends, improper review of claims, delays in access to care, and discrepancies in coverage between Traditional Medicare and the MA program. We fully support the collection of service level data that includes the requested service code, decision rationale, whether internal plan criteria were applied, applicable dates (e.g., date requested, decision date), reviewer qualifications, and whether the appeal was upheld or overturned:

- *Decision Rationale*: We believe that the decision rationale data reported to CMS should be as detailed as possible. Requiring MA plans simply to report whether a claim was denied based on "medical necessity" does not provide sufficient information to ascertain whether the claim was inappropriately denied.

- *Internal Plan Criteria*: We encourage CMS to collect data on the use of proprietary clinical decision support tools. As stated above, CMS has already adopted restrictions on MA plans' use of these tool when Traditional Medicare coverage criteria exist. However, we are aware of MA plans still inappropriately denying claims based on internal plan criteria that are more restrictive than applicable Medicare fee-for-service guidelines. The collection of service level data will aid CMS in identifying areas where MA plans are abusing utilization management tools.

- *Applicable Dates*: Collecting this data would allow CMS to determine whether patients are able to obtain care in a timely manner and whether providers are forced to wait an unreasonable amount of time before receiving a decision on a case.

- *Reviewer Qualifications*: We support the collection of data on reviewer qualifications. Currently, if an MA plan expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the determination must be reviewed by a "physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision." 42 C.F.R. § 422.566(d). We encourage CMS to require the reporting of the reviewer's clinical background, specific certifications, and previous work

experience. This would allow the agency to determine if the MA plan employees or contracts with appropriate health care professionals.

- *Upheld/Overturned*: We believe it is important for CMS to collect information regarding the rate of reversal on appeal, particularly at the third level of appeal where more independent adjudication occurs. We believe that providers are needlessly expending valuable resources to combat frivolous denials of prior authorization and claims. This data would enable the agency to determine whether MA plans are improperly denying claims/requests.

Further, HLS urges CMS to require MA plans to report service level data on denials that are based on artificial intelligence technology, machine learning technology, or clinical decision-making technology. In addition, the agency should mandate that MA plans must provide the aforementioned data in a publicly accessible location and format. Increased transparency will allow CMS, providers, and patients to monitor MA plans more effectively.

HLS greatly appreciates the opportunity to comment on this important data collection initiative. If you have any further questions, please contact me, Desiree Charpentier, at dcharpentier@hlsllc.com.

Sincerely,

Desiree Charpentier, Esq.
Healthcare Legal Solutions

**Service Level Data Collection for Initial Determinations & Appeals – 60-day Comment Period**

Document Identifier: CMS-10905

Please see the following comments/questions:

| Item # | Plan Comments/Questions |
|---|---|
| 1 | When does CMS expect this quarterly reporting requirement to be effective? |
| 2 | Does CMS plan to add these data elements to the current annual Part C Organization Determinations/Reconsiderations (ODR) report or keep this as a separate reporting requirement? If separate, many elements of this reporting is duplicative of the current Part C ODR report along with Encounter Data Reporting. |
| 3 | Please confirm if this reporting applies to both pre-service and payment Part C Organization Determinations/Reconsiderations. |
| 4 | If payment organization determinations are included, does CMS want the payment cases reported at the claim or line level? |
| 5 | When will CMS release field definitions and requirements for this report? |
| 6 | Should this report be pulled by date claim/request is received or date of decision? |
| 7 | Section I - Data Element A - OD Number: Is this the plan's internal claim/case number? |
| 8 | Section I - Data Element B - Contract number and PBP: Does CMS want this combined into 1 data element category or split out? |
| 9 | Section I - Data Element H - Submitted Diagnosis Codes: Does CMS want the primary diagnosis code listed or all codes? Also, dental rarely has diagnosis codes and we'd be interested to know what should be filled out for this category for dental cases. |
| 10 | Section I - Data Element M - Approved or denied: What should partially favorable claims/cases be labeled as? |
| 11 | Section I - Data Element P - Decision Rationale<br>• Would this field be NA for claim approvals that are auto-adjudicated?<br>Section II - Data Element F - Decision Rationale |

Date Submitted: 10/08/2024

| | |
|---|---|
| | • What would CMS like to see in this category? Is CMS looking for coverage criteria, claims edits, etc.? Please provide details. |
| 12 | Section I - Data Element Q - Were internal plan criteria applied: Is this a Y or N answer? |
| 13 | Section II - Data Element G - Reviewer qualifications: What details should be provided for this data element? |
| 14 | Section I - Data Element F, G and H- All codes or just the primary codes? It could be a long list for surgical claims. |
| 15 | Section I – Data Element D- Could NA be an option? For member submitted dental claims, we don't always have this since the member has already provided proof they have paid the bill. |
| 16 | Element Q: Were internal plan criteria applied?<br>Can CMS clarify what is considered "internal plan criteria"? Is this anytime a plan is subjecting criteria that is not reflected in the NCD/LCD/Article?<br>• What about step therapy requirements for Part B drugs – is this considered "internal plan criteria"?<br>• What about network determinations? We will need to coordinate with Medical UM to ensure both areas are reporting the same for network determinations if these are to be included and reported a certain way. |
| 17 | Element T: If element R is yes, was PA request required?<br>• Can CMS provide an example of when they would expect to see element R = "Yes" but element T = "No"? |
| 18 | Element U: If element R is yes, was a voluntary pre-service request received?<br>• Can CMS provide clarification or a definition for "Voluntary pre-service"?<br>• Can CMS provide examples of when they would expect to see Element U reported as "Yes" vs "No"? |

**Kaiser Permanente Comments on**
**Agency Information Collection Activities: Proposed Collection; Comment Request**

**Attention: Document Identifier/OMB Control Number: CMS-10905**
**(OMB control number: 0938-NEW)**

October 8, 2024

*Submitted electronically via regulations.gov*

Kaiser Permanente[1] appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) intention to collect information from the public with respect to the Medicare Part C Service Level Determinations and Appeals published in the *Federal Register* (89 FR 65359) on August 9, 2024 (Form CMS-10905, OMB control number: 0938-NEW).

Kaiser Permanente offers the following recommendations and requests for clarification on the proposed data collection:

***Burden Estimates***

CMS is proposing that Medicare Advantage (MA) plans submit service level data for all Initial Determinations and Appeals on a quarterly basis. CMS estimates that MA plans will require less than 15 minutes per response on average to complete this information collection. In our view, the agency has significantly underestimated the burden on plans to comply with this new onerous quarterly reporting.

We understand and support CMS' goal to obtain key data around coverage decisions and utilization, which can help to ensure plans are meeting CMS guidelines and providing appropriate access to covered services and benefits. We also recognize CMS' authority to collect more granular data related to all plan activities regarding utilization management criteria and processing of coverage requests. In addition, we can appreciate the value in CMS collecting more timely data with greater frequency.

However, we are concerned that the administrative burden to collect and report the new data elements each quarter will be material. The burden estimate CMS provided assumes that data can be pulled from a single system by a single full-time equivalent (FTE); however, this is not the case for plans with multiple contracts, first-tier entities, and systems. This assumption reflects a flawed and incomplete understanding of the operational processes and data systems necessary to meet these requirements. For example, we estimate that Kaiser Permanente requires (1.5 FTEs/860 hours) to complete the annual CMS data validation audit process which has many similarities to

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plans, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 40 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

this data collection effort. This estimate is for the department that manages the audit but does not account for the multiple departments that also contribute to the data validation audit.

Moreover, to appropriately estimate the burden and level of effort required to provide the proposed data set, CMS must clarify whether the reporting requirements apply only to pre-service organization determination data or both pre-service and post-service organization determination data. If it is the latter, further clarification is needed as to whether the post-service organization determination data should be limited to only those claims that are associated with services for which the plan benefits require a prior authorization or to all post-service claims data. If CMS intends to include post-service claims, not only is this duplicative with other current reporting and audit activity (see Duplication of Effort section below) but the feasibility of producing such large data files in the format requested each quarter is highly questionable due to the limitations of Microsoft Excel (i.e., 1M lines per tab) and since providing some of the data elements for post-service would be a very manual process.

***Definitions***

The lack of clarity and detail in the CMS proposal suggests that additional time is needed to develop the requirements to ensure they are adding value and meeting the objectives. We therefore recommend that CMS more clearly define the parameters for each of these elements in the Part C Technical Specifications, similar to what is provided in the current Technical Specification on Grievances and Organization Determinations & Reconsiderations.[2]

For example, we encourage CMS to:

- Provide validation checks that should performed by MA plans prior to data submission
- Define "Initial Determinations" and "voluntary pre-service requests" for the purposes of plan reporting
- Clarify whether all organization determinations are in scope, or only those associated with prior authorizations
- Provide file record layouts for each reporting section

These clarifications will allow MA plans to more accurately assess the burden and to determine the most efficient way to submit data related to decision rationales, as it is difficult to evaluate and quantify reporting burden for data elements that are not clearly defined in Technical Specifications. For example:

- Standardized reporting of Decision Rationale may require major system development, whereas free text reporting may require less.
- Service location and date of service for a pre-service request could be unknown, so reporting would need to allow for that situation.
- Tracking Voluntary Preservice Requests would require system development and staff training to support consistent and reliable methods of reporting.

[2] See, for example, Medicare Part C Reporting Requirements: Technical Specifications Document Contract Year 2024 (OMB 0938-1054), available online at: https://www.cms.gov/files/document/cy2024-part-c-technical-specifications.pdf.

CMS must provide plans with detailed definitions of the proposed data elements so plans can evaluate system limitations and quantify the resources that will be required for both system development and staff training before the reporting can be implemented. We strongly encourage CMS to release draft Technical Specifications prior to soliciting a second round of comments.

***Duplication of Effort***

We recognize CMS' authority to collect more granular data related to all plan activities and processes for requests for items or services; however, the agency has recently adopted or proposed many new reporting requirements focused on Utilization Management and some are duplicative. Therefore, we recommend CMS either significantly streamline reporting or more thoroughly evaluate whether existing data/reporting can be used by the agency to meet its stated goals. At a minimum, CMS should articulate the basis for each unique new reporting requirement and its marginal value.

Apparent examples of duplication with existing requirements include:

- As part of the "Improving Prior Authorization Processes" component of the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F), plans are required to report on new metrics including percentages of prior authorization requests approved and denied for both standard and expedited requests. This requirement goes into effect on January 1, 2026 and plans must publicly report the first set of metrics by March 2026. (42 CFR 422.122(c)(2)(3))
- Prior Authorization data elements are part of the newly required Annual Health Equity Analysis, which requires percentages of prior authorization requests approved and denied for both standard and expedited requests. (§ 422.137)
- Annual Part C reporting of Organization Determinations requires counts for approved and denied decisions, which are supported during annual data validation by Date Request Received and Date of Decision—both of these elements are also included in the Service Level Data Collection. (Medicare Part C Reporting Requirements Contract Year 2024; OMB 0938-1054)
- The Part C Organization Determinations, Appeals and Grievances (ODAG) protocol and data request include universe tables with similar data fields to provide consistent information. The Appeals section of the Service Level Data Collection is entirely duplicative with the ODAG protocol, except for elements A and G. Utilizing existing Program Audit universe tables/formats will reduce the burden on plans for creating new versions. (ODAG Protocol and Data Request: Service Level Data Collection for Initial Determinations and Appeals; CMS-10905, OMB 0938-1395)
- CMS recently published proposed Utilization Management annual data collection specifications and audit protocols, which drive at the same underlying requirements that serve as the basis for this proposed reporting. In fact, the audit protocols include a layout for an Impact Analysis that directly duplicates many of the elements required for this reporting. (Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request; CMS-10913; OBM control number: 0938–New)

Beyond these competing data requests from CMS, we note that several MA plans also recently received requests from the Office of the Inspector General and the Government Accountability

Office focused on Utilization Management and Prior Authorization requirements. As a result, MA plans are providing similar data and information to numerous parties. We recommend that CMS consider how it can create more transparency, harness existing data submissions, and consider which data collection mechanism represents the most effective avenue for oversight in order to avoid duplicative initiatives that require the submission of the same information multiple times per year.

***Effective Date***

Should CMS proceed with its proposal to collect these data, we strongly recommend that the agency delay implementation of the new reporting requirements until at least the 2026 plan year. Providing plans with additional lead time will support more accurate implementation and data reporting since MA plans will need to make significant changes to administrative processes, programming and technology infrastructure for their own systems as well as their first-tier entities.

October 8, 2024

Centers for Medicare and Medicaid Services
7500 Security Boulevard
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Mail Stop C4-26-05
Baltimore, MD 21244-1850

*Comments submitted electronically*

LeadingAge is grateful for the opportunity to offer our support for and provide input into CMS' Service Level Data Collection for Initial Determinations and Appeals (CMS-10905). As an organization representing more than 5,400 nonprofit and mission driven aging services providers and other organizations who touch millions of Medicare beneficiaries' lives every day, LeadingAge has long advocated for CMS to collect additional information regarding Medicare Advantage plans prior authorization determinations for services to ensure accountability and transparency in these processes.

We appreciated the many clarifications contained within the CY2024 MA policy and technical rule around prior authorizations and utilization management. This data collection effort represents an important next step in determining if the CY2024 MA policy clarifications have had an effect on ensuring beneficiary access to medically necessary care and can also serve as an enforcement tool.

We are supportive of the thoughtful list of data points CMS has proposed for collection. For example, the inclusion of data on when a request is received and when the decision is made can show how long these processes are taking, whether they are delaying access to needed care and services, and if plans need to dedicate additional resources to these activities. In addition, by collecting site of the service information, CMS will be able to analyze whether decision timelines and authorization decisions vary across types of services, geographies or size of plan.

To ensure a complete picture of these service determinations and their impacts on beneficiaries' access to care and services, we have identified some areas that require further clarification or could be enhanced:

- The data collection appears to only collect data on Initial determinations; however, this is but one piece of the puzzle about beneficiary access to services. Particularly in skilled nursing facility (SNF) and home health (HH) services, there are multiple subsequent requests for authorization to continue care, which are sometimes called concurrent reviews or re-authorizations. It is these requests where providers and plans do not always agree on the beneficiary's need for continued services. We recommend CMS also collect and track these subsequent requests and determinations in addition to initial prior authorizations. Together, these data will provide a more complete picture of whether prior authorizations are covering a "course of treatment" or if the cycle of repeated authorizations poses unnecessary barriers to care or excessive administrative burden. It will also be more representative of an MA enrollee's care journey and where potential obstacles exist.

- Section I, item K – Can you clarify what information is sought related to "date of service?" For Skilled Nursing Facilities (SNFs), typically, this care is provided over a series of consecutive days vs. a physician visit that is a single date in time. For home health (HH) care, visits may be spread out over as much as a 30-day period. Therefore, we are curious if CMS is trying to capture what date a service begins after being authorized or if instead, CMS seeks to understand service utilization patterns by provider type based upon these MA plan service determinations. We believe there is benefit in understanding both situations. The initiation of service in relation to plan authorization for the services offers insights into where delays may occur. For example, some of our SNF and HH members have reported circumstances where a plan decision takes so long that the first provider is no longer available to provide the requested service. In these circumstances, it is our understanding that the prior authorization process must start over with a new request for the same service but authorized for a different provider further delaying the next level of care. We also think there is value in understanding the duration of services provided to better understand service delivery patterns, such as the number of SNF days or HH visits approved per MA plan authorization and how they compare to care duration within traditional Medicare.
- Section I, Item I – Could CMS clarify whether this refers to the "processing priority" requested by the provider or the one determined by the MA plan? In recent months, we have heard of more cases where plans are treating requests as standard when they were previously considered expedited. It might be beneficial to know if a provider submitting the request asked for it to be expedited and it was treated as standard request.
- Section I, Item P requires the plan to report the "decision rationale." Does CMS envision this being a drop-down list of standard denial reasons or would this be free form? We recommend that this item or a related item capture the actual rationale language contained in the letter to the enrollee to ensure it provides an adequate level of detail for the beneficiary to understand the decision and determine if an appeal is warranted.
- Section I, item Q – If the answer is "yes" to this item, it seems that there should be a follow up item where the plan cites the internal coverage criteria used. This could provide CMS with important information to examine the frequency with which certain internal coverage criteria are utilized by plans and whether further clarification in these areas may be warranted.

**These Data Should Be Published Annually**

It would be a lost opportunity if this data was not shared with the public and consumers in an easily digestible way to help them understand and compare their MA plan options across plans and with traditional Medicare. While not within the scope of this data collection proposal, we would recommend CMS consider annually reporting this data in one or more of the following ways: 1) a single report that compares plans across metrics; 2) include key data points by service category (e.g. post-acute care) on Medicare plan finder to assist consumer decision making; and 3) incorporate key metrics in the MA Star Rating program as part of beneficiary experience domain.

We understand that the Interoperability and Prior Authorization rule (CMS-0057-f), finalized in April 2024, calls for plans to report on some of these same items but instead of reporting it to CMS, the rule calls for plans to report this data on their individual websites. We believe this will be much less effective in helping consumers evaluate their plan choices and in holding plans accountable for regulatory compliance.

Consumers have limited information upon which to base their decision about whether to receive their Medicare benefits through traditional Medicare or a MA plan. As MedPAC and others have noted, the

quality measures for MA plans require a new look. Consumers need to understand how their care experience may be different between traditional Medicare and MA plans, and among MA plans. For this reason, we recommend CMS publish key plan-level metrics from this data collection effort that describes the care experience a consumer can expect and tracks comparable, key quality measures required in Medicare such as those reported by providers under the IMPACT Act so that outcomes can more readily be compared between traditional Medicare and MA by consumers and policymakers.

**Recommendation:** We recommend reporting the following information by plan on Medicare plan finder or make it available in a report for the public as a consumer care experience scorecard. We ask that CMS also consider breaking out this information by broad service categories or provider types (e.g., post-acute care, acute care, primary, etc. or SNF, HH, hospital, etc.) as we believe this would be more informative of where denials are most prevalent, and types of care or services are being delayed or prevented. It may also be useful to report the top reasons for prior authorization denials by plan to correct inappropriate barriers to medically necessary care and services. Such a report may include:

- **% of prior authorizations denied.**
- **% of denials appealed and overturned.**
- **Number of days between care/service authorization and receipt of post-acute care services by service**. This information could provide another view of network adequacy and access to care for MA enrollees. Our home health providers have reported that some MA plans will only approve an initial visit and then require an authorization for future visits after they have reviewed documentation and notes from the initial visit. This practice often delays receipt of additional home health services by up to a week.
- **Average length of stay in post-acute care (PAC) by type** (e.g., SNF, LTCH, IRF). By collecting this data and rehospitalization information, we could evaluate whether plans' choice to reduce length of stay results in better outcomes for the individual.
- **Average number of home health visits per episode**. Like length of stay, it would be important to be able to evaluate whether fewer visits result in better long-term outcomes for the individual.

Additionally, CMS might also consider whether some of this data and corresponding analysis should be added to the MA Star Rating Program as part of a beneficiary experience domain.

**Data for Oversight and Enforcement**

We agree that these data can play a critical role in ensuring plan compliance with rules and in identifying trends or issues that require further attention. For example, if insufficient documentation is identified as a main reason for many denials and delays in access to needed care, CMS could audit plan records to determine if the correct documentation was present (as the OIG report found in numerous cases) and missed or never provided. Plans are not incentivized to undertake such a review, as it could lead to approving more services, and in turn, increasing plan care costs. Understanding the barriers to appropriate prior authorization approvals for medically necessary care can help identify needed policy changes to ensure timely and equitable access to needed services. These data may be able to help us identify underlying issues that could/should be corrected through education of plans and/or providers to ensure beneficiaries' access to care occurs without unnecessary delays.

Therefore, this data should be audited as well as reported. We recognize that this could create a significant burden for CMS and may require additional resources to be executed effectively. Our recommendation is that audits be conducted based on the risk of the contract and the identification of

outliers to reduce the operational burden that conducting audits on a data set of this nature could create.

Thank you for the opportunity to share some of our ideas for how the proposed data collection on service authorizations and determinations could be enhanced to achieve its goals to ensure compliance with regulations and guidance and support enforcement. These data are critical for transparency as more and more beneficiaries shift to the MA program to ensure they have access to the Medicare A and B services to which they are entitled. As always, please reach out with questions.

Sincerely,

Nicole O. Fallon

Vice President, Integrated Services & Managed Care

LeadingAge

*LeadingAge represents more than 5,400 nonprofit and mission-driven aging services providers and other organizations that touch millions of lives every day. Alongside our members and 36 partners in 41 states, we use applied research, advocacy, education, and community-building to make America a better place to grow old. Our membership encompasses the continuum of services for people as they age, including those with disabilities. We bring together the most inventive minds in the field to lead and innovate solutions that support older adults wherever they call home. For more information visit leadingage.org.*

October 8, 2024
Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

***Submitted electronically***

**Re: Agency Information Collection Activities; Proposed Collection; Comment Request – Service Level Data Collection for Initial Determinations and Appeals (CMS-10905)**

Dear Administrator Brooks-LaSure,

The National Association of Long Term Hospitals (NALTH) is the only hospital trade association in the nation devoted exclusively to the needs of medically complex patients who require services provided by long-term acute care hospitals (LTCHs). NALTH members include the nation's leading LTCHs, including free-standing, hospital-within-hospital, for-profit, and non-profit LTCHs.

Over the years, NALTH has shared critical feedback with CMS on the Medicare Advantage (MA) prior authorization process and has documented prior authorization denials that have resulted in the inability of Medicare beneficiaries to access medically necessary and appropriate LTCH care.

NALTH greatly appreciates CMS's efforts to improve the MA prior authorization process, and we strongly support CMS's efforts to expand the reporting requirements of MA plans regarding their use of prior authorization in Information Collection on Service Level Data Collection for Initial Determinations and Appeals (CMS-10905).

NALTH believes that the collection of this data will help ensure that Medicare beneficiaries enrolled in MA are able to receive medically necessary LTCH care. We urge CMS to finalize its data collection plan to increase transparency around prior authorization in Medicare Advantage. We provide more detailed comments below.

## CMS Proposed Information Collection

Under this proposed Information Collection Request (ICR), CMS seeks to expand the prior authorization and related utilization management reporting requirements for MA plans, by instituting a quarterly reporting requirement. Under this regulation, MA plans would be required to report service-level data elements like:

- The requested service code(s) and name of the associated service(s),
- The diagnosis code(s) submitted with the request for service(s),
- Whether the determination was processed as a standard or expedited request,
- Whether the provider was contracted with the MA plan (i.e., "in-network" or not),
- The plan's decision on the request (approved or denied),
- The "decision rationale," and
- Whether internal plan criteria were applied.

MA plans would also be required to submit data for each appeal, including the approval/denial, the processing priority (standard or expedited), the decision rationale upon reconsideration, and the "reviewer qualifications."

**NALTH strongly supports CMS's efforts to provide clarity and transparency in the MA prior authorization process. Collecting data on initial determinations and appeals will allow CMS to better understand and evaluate MA plan's prior authorization practices and ensure that those who need access to an LTCH, can receive care in an LTCH when care is clinically appropriate.**

## Specific Data Elements Included in CMS' Information Collection Request

Generally, NALTH supports the proposed data elements for collection from MA plans. However, we believe that additional detail should be provided to ensure that the data accurately meets the standard the agency is expecting and provides meaningful, actionable information.

### Decision Rationale (Elements I-P and II-F)

While CMS proposes to collect the "decision rationale" for both initial determinations and appeals, NALTH requests that CMS provide clear and standard approaches to report the decision rationale. Currently, MA plans are required to "state the specific reasons for the denial" when the organization denies a service or item and communicate this to the beneficiary in writing.[1] However, providers and patients have long reported that the denial notices provided by MA plans do not provide the beneficiary with the specific reason for denial and include language that does not indicate any individualized assessment of the patient's medical or functional needs. In addition, NALTH members have documented that MA plan denial letters frequently incorrectly cite requirements or regulations. For example, NALTH members have received denial letters from MA plans stating that transfer to an LTCH was not medically necessary because there are

[1] 42 C.F.R. § 422.568(e)(2).

no required medical services in a LTCH that the patient is not receiving in the short-term acute care hospital. These denials improperly disregard the physician's judgment about what is best for the patient. Taken to its logical extreme, an MA need never approve care in an LTCH setting.

**We urge CMS to require that MA plans submit detailed, patient-specific "decision rationale" for both initial determinations and plan reconsiderations. We also request that CMS have a standardized approach to reporting rationale and that it links back to specific Medicare regulations and requirements.**

Reviewer Qualifications (Element II-G)

In the 2024 MA Final Rule, CMS required the expertise of the physician or healthcare professional reviewing a coverage determination be relevant to the item or service requested, if the plan expects to issue a denial. However, some providers have reported coverage denials that do not meet this requirement. In this ICR, CMS is proposing to collect "reviewer qualifications" when a plan makes a determination at the reconsideration level. **We urge CMS to provide additional clarity on reviewer qualifications (i.e., specialty of reviewing clinician, relevant certification(s), and/or detailing any additional training that would satisfy the current regulatory standard) in their data collection.**

## Public Reporting of Newly Collected Data

Lastly, NALTH wishes to emphasize the importance publicly report relevant MA data. In the past few years, CMS has made significant efforts to provide clarity and transparency in the prior authorization process, and NALTH urges the agency to continue by publishing a de-identified version of these data elements on a CMS-supported, consumer-facing site, like Care Compare. Additionally, CMS should incorporate the newly collected data into quality reporting programs, such as MA Organization Star Ratings, to ensure that payers are held accountable for their performance.

**Overall, NALTH would like to commend CMS on the significant steps it has taken towards improving patients access and supports all of CMS's improvements to the utilization management policies used by MA plans. We are ready to work with CMS to ensure that those who need access to an LTCH, whether in MA or Traditional Medicare, can receive care in an LTCH when a patient, family member, and treating physician feel LTCH care is clinically appropriate.**

* * *

NALTH appreciates the opportunity to submit these comments.

Sincerely,

EPrettyman, Psy.D.

Ed Prettyman, PsyD
President
National Association of Long Term Hospitals

NARA
The National Association of Rehabilitation Providers and Agencies

October 8, 2024

ELECTRONIC SUBMISSION VIA www.regulations.gov

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

**RE: Agency Information Collection Activities: Proposed Collection; Comment Request Service Level Data Collection for Medicare Advantage Plans (CMS-10905)(OMB Control Number: 0938-New)**

Dear Administrator Brooks-LaSure:

The National Association of Rehabilitation Providers and Agencies (NARA) represents over 90,000 physical therapists (PT), occupational therapists (OT), and speech language pathologists (SLP) through our member organizations who provide therapy across the United States to Medicare beneficiaries. They provide therapy in all settings across the continuum such as outpatient clinics, skilled nursing facilities (SNFs), assisted living facilities (ALFs), retirement communities, hospital inpatient and outpatient, and in the beneficiary's home. As a member-driven organization, NARA promotes best practice and business success of physical therapy, occupational therapy, and speech-language pathology providers through education, support, and advocacy. NARA's membership demographics give us a unique insight into payment and quality programs of the Centers for Medicare and Medicaid Services ("CMS"). We appreciate the opportunity to provide the comments to the Centers for Medicare and Medicaid Services ("CMS") in response to its intent to collect service level data on Medicare Advantage ("MA") determinations and appeals.[1]

NARA members appreciate CMS for taking the necessary steps to monitor Medicare Advantage (MA) plan compliance with Medicare requirements and enhance transparency in the MA program. We support the collection of more detailed service line data and believe it is essential to the program's overall success and ensures CMS' ability to safeguard vital MA services beneficiaries are entitled to under the Medicare program. We offer the following recommendations to assist MA plans in identifying areas of improvement with ways to

[1] Agency Information Collection Activities: Proposed Collection; Comment Request, CMS-10905- Service Level Data Collection for Initial Determinations and Appeals, 89 Fed. Reg. 65,359 (Aug. 9, 2024).

ensure MA plans are held accountable for misusing or abusing utilization management tools.

**Benefits of Collecting Setting-Specific Data**

NARA strongly supports the collection of service line data under MA plans. We believe gathering data at this more detailed level will provide a clearer understanding of how the MA program functions, enabling more informed decision-making, targeted improvements, and equitable care delivery. This, in turn, will enhance the program's overall quality and efficiency. Specifically, we believe the collection of setting-specific data would enable a granular assessment of performance across different care settings, particularly in the post-acute care settings, including skilled nursing facilities (SNFs), home health agencies (HHA), and outpatient clinics. NARA believes this level of specificity would allow for more precise measurement of coverage denials and appeals within each service line, leading to more targeted quality improvement initiatives to ensure beneficiaries are receiving the medically necessary care they need in a timely manner.

The addition of detailed service line data would significantly assist CMS in identifying disparities in access to and quality of care among different settings. By identifying these potential gaps in service delivery and outcomes across the post-acute service lines, MA plans would be able to develop specific interventions, instead of a one-size-fits all approach, to address disparities and improve equity in healthcare access and quality.

Additionally, NARA believes service line data is critical for strategic planning and policy development. This data would provide insight into utilization trends, identify emerging needs, and support the creation of policies to address specific challenges within the different service lines. This data-driven approach would make certain policies are relevant and effective in improving access to quality care across the various specialties.

Finally, we believe comprehensive service line data would enhance transparency and accountability by providing a clear view of how different service lines perform. This transparency would help CMS better understand the quality of care being provided in post-acute care settings, thus having the ability to hold MA plans more accountable for their performance. Accurate service line data would support effective resource allocation by identifying which areas require more support or investment. This information would help MA plans allocate resources efficiently, ensuring high-need service lines receive appropriate funding and support to enhance care delivery and patient outcomes.

**Prior Authorization**

NARA applauds CMS for its recent regulatory action to create more safeguards for beneficiary coverage by limiting MA organizations from inappropriately engaging utilization management tools such as prior authorizations, which create unnecessary delays or denies of care. The MA final rules for Contract Years 2024 and 2025, with established guardrails for MA plans will help to prevent beneficiaries from barriers to access to post-acute care services. Most the barriers are caused by restrictive coverage policies, improper use of prior

authorization, or other utilization management techniques and administrative burdens.[2] The recently finalized Advancing Interoperability and Improving Prior Authorization Processes rule helps to build on those protections and addresses key issues with prior authorization including requiring written reasons for denials, shortening timeframes for decisions of appeals, and requiring greater transparency from payers.[3]

Our members report that prior authorization continues to be a serious impediment to care for beneficiaries with disabilities and individuals seeking medical rehabilitative care. Even with the patient protections that took effect January 1, 2024, our members continue to experience problems with prior authorization denials and overly restrictive hurdles in MA plans. NARA encourages CMS to continue to enforce the new regulations and audit MA plans to ensure beneficiaries can benefit from these new regulations in practice as intended. An example that is currently happening and creating significant barriers for beneficiaries accessing rehabilitation is UnitedHealthcare's (UHC) newly implemented prior authorization requirement for MA plans. This requirement was announced on August 1, 2024, and implemented just 31 days later on September 1, 2024. Since its implementation, there continues to be a great deal of misunderstanding regarding the requirements of what place of services (POS) settings this impacted, and providers were unable to get accurate clarification from UHC provider representatives. NARA has received reports of significant processing issues and delayed care for beneficiary as a result of conflicting POS information, the inability to access portal due to necessary passwords not being provided by UHC/Optum, the portal not available to providers to submit on September 1, requests which were submitted disappearing from the portal without explanation or notification, and beneficiaries being unaware that their rehabilitation services now require prior authorization due to lack of proper notification. Since implementation, our members are experiencing an average processing time by UHC/Optum of 10 – 13 calendar days. In addition, some NARA members are being notified of only partial approvals for beneficiaries citing Optum Utilization Management Policy #497, which does not provide any specific reasons for the denial while others are experiencing claims denied for lack of pre-certification when prior authorization had been approved which creates additional administrative burden for an improper denial process. NARA encourages CMS to closely monitor this type of change in behavior by MA payers to ensure proper communication is provided to beneficiaries when their ability to access benefits become more restrictive , access to medically necessary services is likely to be delayed due to a new prior authorization process or when unclear

[2] "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." *Federal Register* 88:70 (April 12. 2023) at 22120 et seq.; "Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." *Federal Register* 89:79 (April 23, 2024) at 30448.

[3] "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program." *Federal Register* 89:27 (February 8, 2024) at 8758 et seq.

requirements are communicated to providers, partial approvals or denials do not cite specific reasons, and payers improperly deny claims causing financial and administrative burden to providers.

NARA supports increased transparency from MA plans about their use of prior authorization and metrics on denials and approvals. As established in the Advancing Interoperability and Improving Prior Authorization Processes final rule, beginning in 2026, MA plans will be required to publicly report certain prior authorization metrics annually by posting them on the plan website. CMS also established in the Contract 2025 final rule that MA plans will be required to conduct an annual health equity analysis of the use of prior authorization and its impact on enrollees with one or more social risk factors at the plan level. We strongly encourage CMS to require the collection of service line level data for these publicly reported metrics and analysis to help assess care provided in SNFs, HHAs, physician offices, outpatient therapy services, and other sites of care. If the service line data is collected instead of receiving and analyzing MA data in the aggregate, CMS would be able to view a much more site-specific picture resulting in the ability to better compare multiple payers' prior authorization metrics at the service line level. Only with this more granular level of specificity will CMS be able to assess which services are routinely denied, appealed, and overturned in favor of patients and providers, leading to reforms to accelerate access to appropriate, timely, and necessary care.

According to feedback from our NARA members, we are concerned that prior authorization denials in several post-acute care settings are more common than in other settings, as has been recognized in a 2022 OIG report, and that these disparities in approvals are largely concealed with the current aggregated data reporting requirement.[4] It is essential for beneficiaries with disabilities, illnesses, injuries, and chronic conditions to receive medical rehabilitation services timely in post-acute care, and the well-documented denials of care for this at-risk population demands further examination. CMS could improve health equity for beneficiaries by requiring analysis at the level of items and services instead of aggregating for all items and services. NARA encourages CMS to request this data retroactively over several contract years for these areas of care to determine if there is a longstanding discriminatory patterns of care denials. Only this level of specificity will allow CMS to assess which items are routinely denied, appealed, and overturned in favor of patients and providers.

**Reviewer Qualifications**

NARA advocates for the collection of data on reviewer qualifications when making an initial medical necessity determination. Under current regulations, if a MA plan intends to issue a partial or full denial based on a medical necessity decision on the initial review, the determination must be reviewed by a "physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the

[4] U.S. Department of Health and Human Services, Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care; Report (OEI-09-18-00260) (Apr. 2022).

services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision."[5] NARA encourages CMS to require the reporting of the reviewer's clinical background, specific certifications, and previous work experience. This requirement would allow CMS to determine if the MA plan employs or contracts with appropriate health care professionals. Further NARA believes that CMS should require that the reviewer's credentials and NPI number be provided on all determinations.

**Network Adequacy**

NARA believes MA plans should provide more information to beneficiaries about their provider networks through provider directories available on publicly accessible websites. Provider networks are a critical component of Medicare Advantage plans, directly impacting beneficiaries access to care. Insufficient networks can limit provider choice and accessibility, particularly in rural and underserved areas. However, there is insufficient publicly available data on the composition and adequacy of provider networks within MA plans.

Enhanced transparency in provider network data will enable beneficiaries to make informed choices regarding their healthcare plans and ensure MA plans maintain networks that meet the healthcare needs of their enrollees. NARA recommends CMS enhance transparency for beneficiaries by requiring MA plans to report data on geographic distribution and network sufficiency of all services, including post-acute rehabilitation, to meet the needs of enrollees, particularly in rural and underserved areas. It would also be helpful to beneficiaries considering the choice between Traditional Medicare or an MA plan to see comparative metrics on provider access in their geographic area. This geographic data is increasingly important as healthcare providers and hospitals drop MA plans due to excessive prior authorization denials, low payment rates, and excessively slow and incomplete credentialing processes.

We thank you for the opportunity to provide comments related to this proposed rule. Should you have any questions concerning these comments, please contact Christie Sheets-Covington, NARA Executive Director at christie.sheets@naranet.org.

Respectfully submitted,

Kelly Cooney, M.A., CCC-SLP, CHC
President
National Association of Rehabilitation Providers and Agencies

1570 Midway Pl.
Menasha, WI 54952

October 8, 2024

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
CMS-10905; OMB 0938-New
Submitted electronically: www.regulations.gov

Re: CMS-10905; 0938-New; Service Level Data Collection for Initial Determinations and Appeals

To Whom it May Concern:

Network Health Plan, Network Health Administrative Services, LLC, Network Health Third Party Administrator, and Network Health Insurance Corporation (together "NH") appreciates the opportunity to provide feedback to the Centers for Medicare and Medicaid Services ("CMS") on the proposed changes to the Service Level Data Collection for Initial Determinations and Appeals published on August 9, 2024, in the Federal Register.

CMS requested feedback by October 8, 2024. The following is NH's response.

**Service Level Data Collection for Initial Determinations and Appeals**

CMS Proposal:
CMS is proposing this new data collection on key data elements that health plans would be required to provide to CMS about the utilization of benefits, to enhance CMS's audit activities, and ensure appropriate access to covered services and benefits. CMS is soliciting input on how health plans can most efficiently provide and submit information to CMS on their plan decision rationales for initial determinations and appeals. CMS is proposing to collect the data elements as noted in the "Service Level Data Collection" document included in the information collection package. The data elements for all appeals would include applicable initial determination number, whether approved or denied, date request received, date of decision, processing priority (standard or expedited), decision rationale, and reviewer qualifications. CMS acknowledges that this new data collection increases Medicare Advantage organizations' ("MAOs") burden and this information is already required to be provided in Medicare beneficiary correspondence. CMS also wants to receive this information.

*NH Response:*
*The request for decision rationales for initial determinations and appeals differs and is specific to each case. Our plan captures decision rationales in a note (vs. a reportable field), which would be difficult to extract into a report depending on the volume of information documented per case.*

*To comply with the requirements in this information collection, some plans may need to create additional reporting fields in their systems to capture the required data; otherwise, the data*

*elements CMS requests would need to be extracted and reported manually. Without the additional reporting fields added, administrative costs will increase impacting end health plan user workflow by requiring manual entry of the required data. This will increase the time to capture the data and potentially increase the margin for error, which will make utilization review less efficient and increase administrative costs if any rework needs to be completed; this will have an influence on all costs. The best way for CMS to receive decision rationales for initial determinations and appeals is how CMS currently receives similar data today, through CMS' program audit.*

CMS Proposal:
The data is to be reported on a quarterly basis at the service level.

*NH Response:*
*NH understands CMS proposes the required data to be reported quarterly; however, NH is concerned how this will work with existing required reporting timeframes (e.g., annual CMS reporting, grievance data requirements and Part C Data Validation), but with a shorter turnaround time.*

*Overall Recommendation:*

*NH is concerned this information will be administratively burdensome to gather manually and is similar to the data required in current reports (i.e. Part C Data Validation, CMS universe reporting) submitted to CMS. If CMS proceeds to adopt this reporting requirement, NH recommends the data be collected annually (vs. quarterly) to minimize the burden and not be applicable until at least 2026 to allow time for system changes and testing. In a subsequent CMS public comment request, titled "Medicare Part C UM Annual Data Submission and Audit Protocols Data Request", CMS is also requesting data elements that would require health plans submit similar data annually. NH is recommending both data collections be in one comprehensive universe to minimize burden on plans.*

NH appreciates CMS's consideration of our and other stakeholders' feedback to the Service Level Data Collection for Initial Determinations and Appeals.

Respectfully submitted,

Chia Lee

Chia Lee
Regulatory Support Administrator

THE ORTHOTIC AND PROSTHETIC ALLIANCE

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October 8, 2024

**SUBMITTED ELECTRONICALLY VIA WWW.REGULATIONS.GOV**

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

**RE: O&P Alliance Comments on Service Level Data Collection for Initial Determinations and Appeals (CMS-10905) (OMB Control Number: 0938-New)**

Dear Administrator Brooks-LaSure:

On behalf of the Orthotic and Prosthetic Alliance (the "O&P Alliance"), a coalition of five major national orthotic and prosthetic ("O&P") organizations representing over 13,000 O&P professionals and 4,500 accredited O&P facilities, we appreciate the opportunity to submit comments on the Centers for Medicare and Medicaid Services' ("CMS's") intent to collect service level data on Medicare Advantage ("MA") determinations and appeals.[1]

The O&P Alliance is committed to ensuring that Medicare beneficiaries, including MA enrollees, have timely access to reasonable and medically necessary O&P care from qualified practitioners and suppliers. To this end, we strongly support CMS's efforts to enhance transparency in the MA program, including the collection of detailed service level data. This collection effort will help the agency monitor whether MA plans are improperly denying claims for orthoses and prostheses. We respectfully offer the following recommendations to help ensure that MA plans cover the same prostheses and orthoses as those included in fee-for-service Medicare. In addition, we urge CMS to exercise greater oversight of MA plans to ensure that these plans do not employ utilization management techniques (e.g. prior authorization) or other clinical guidelines in a manner that improperly restricts access to O&P care.

[1] Agency Information Collection Activities: Proposed Collection; Comment Request, CMS-10905- Service Level Data Collection for Initial Determinations and Appeals, 89 Fed. Reg. 65,359 (Aug. 9, 2024).

**Access to O&P Care**

If the Medicare fee-for-service program covers an orthosis or prosthesis, MA plans must cover at a minimum, the equivalent orthosis or prosthesis. Medicare regulations and the Medicare Managed Care Manual ("MMCM") are clear that MA plans must provide all Medicare-covered items and services, including orthoses and prostheses.[2] Notwithstanding these clear directives, MA plans have employed utilization management techniques and other clinical care guidelines that have the effect of improperly restricting access to O&P care that would have been otherwise available to Medicare fee-for-service beneficiaries.

We hear consistent feedback from O&P clinical practices, prosthetists, orthotists and patients that MA plans regularly employ tactics to delay and deny O&P patient care. If MA enrollees cannot receive authorization for O&P care available in the fee-for-service program, those beneficiaries are forced to wait months for medically necessary, physician-prescribed treatment while they navigate multiple appeal levels or abandon the MA plan and join the Medicare fee-for-service program. The alternative is to pay out-of-pocket or simply go without the O&P care deemed medically necessary by their physician and O&P clinician. This establishes an inequitable healthcare system that deprives MA plan enrollees of their right to the same coverage as traditional Medicare beneficiaries.

**Additional Oversight of MA Plans Is Needed**

The O&P Alliance strongly supports the agency's intent to collect comprehensive service level data from MA plans, including requested service codes, reviewer qualifications, dates (e.g., date requested, decision date), and whether the appeal was upheld or overturned. Gathering this data is crucial to help the agency identify improper or unnecessary reviews of claims, delays in access to care, unnecessary denials, and utilization trends.

Requested Service Code: The O&P Alliance applauds the level of specificity included in the service level data for initial determinations. We support the collection of requested service codes at the Healthcare Common Procedure Coding System ("HCPCS") level. As you are aware, orthotists and prosthetists currently bill their services based on a series of HCPCS "L" codes at the time an orthosis or prosthesis is delivered to the patient. Gathering this data at the HCPCS level will ensure that O&P services are not lumped in with durable medical equipment described by "E" codes, for instance. The large number of DME claims would skew the data for orthotics and prosthetics.

Reviewer Qualifications: Under existing law, if an MA plan expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the determination must be reviewed by a "physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision." 42 C.F.R. § 422.566(d). We encourage CMS to collect data on

[2] 42 C.F.R. § 422.101(a); Medicare Managed Care Manual, Pub. 100-16, Ch. 4, § 10.12.

reviewer qualifications, including the reviewer's clinical background and previous work experience. We believe this information will help CMS determine if MA plans are appropriately staffed.

Applicable Dates: The O&P Alliances supports the collection of data that would allow the agency to ascertain whether patients are able to obtain care in a timely manner. This data will also shed light on whether practitioners are forced to spend time appealing improper denials.

Upheld/Overturned: The O&P Alliance is concerned that MA plans are improperly denying prior authorization requests and claims for payment, forcing practitioners to take a loss or appeal the frivolous denial. Collecting data on the rate of reversal on appeal will help the agency determine whether MA plans are improperly reviewing claims for O&P care.

In addition, we strongly believe that this data should be made public so that patients and practitioners can better monitor MA plans. Further, to ensure the equitable administration of Medicare benefits, CMS should encourage MA plans to regularly solicit feedback from O&P stakeholders regarding MA policies, audits, and the appeal process.

Thank you for your consideration of our comments. To contact the O&P Alliance directly, please contact O&P Alliance Counsel, Peter Thomas (Peter.Thomas@powerslaw.com) or Leela Baggett (Leela.Baggett@powerslaw.com).

Sincerely,

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# PUBLIC SUBMISSION

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## Submitter Information

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## General Comment

The documentation provided has been reviewed across multiple departments that would be impacted by the reporting request and found more detail to reporting requirements would be needed upon finalizing the rule.
- Would this reporting include Part D or is this only for Part C determinations and appeals.
- When would the reporting requirement begin and what will the look back period be?
- How often would the reporting be required (monthly, quarterly, yearly)?