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Latest Developments in Medicare Provider Enrollment

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Topics for Discussion

- Update to the Medicare enrollment regulation for required disclosures of affiliations
- CMS upcoming written guidance on comingling/sharing of space
- PPS hospital claim edits for certain hospital outpatient departments
- MedPac's recommendation for elimination of "incident to" billing for PAs and NPs
- Changes to the receipt date and signature requirements impacting Medicare enrollment applications
- Upcoming revisions to completion of paper applications

Topics for Discussion

- Re-implementation of CMS deactivation policy
- Changes to CMS policy regarding reactivations of Medicare enrollments due to missed revalidations
- Revisions to policies regarding Independent Diagnostic Testing Facilities (IDTFs)

Change in Medicare enrollment regulations

- In the March 1, 2016 Federal Register, CMS published a proposed rule that would implement sections of the ACA that require Medicare, Medicaid and CHIP providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers. This regulation had not been finalized due to President Trump's Executive Order prohibiting new health care regulations from finalization until review by his administration has been completed. This proposed rule was set to expire March 1, 2019; however, due to the complexity of the rule and the scope of the comments received, the timeline for publication of the final rule was extended for one (1) year to March 1, 2020.
- In the September 10, 2019 Federal Register, CMS published the final rule, which will become effective November 4, 2019. An additional comment period has been established through the effective date for issuance of sub-regulatory guidance related to implementation.

Change in Medicare enrollment regulations

- The major provisions of the final rule include the following:
 - Required disclosures to include any current or previous direct or indirect affiliation with a provider or supplier that has uncollected debt, has been or is subject to a payment suspension under a federal health care program, has been excluded from Medicare, Medicaid or CHIP, or has had its Medicare, Medicaid or CHIP billing privileges denied or revoked.
 - Denial or revocation of a provider's or supplier's Medicare enrollment if CMS determines that the provider or supplier is currently revoked under a different name, numerical identifier or business identity or if a provider or supplier billed for services performed from a location that it knew or should have known did not comply with Medicare enrollment requirements.
 - Increase of the existing maximum re-enrollment bar from 3 to 10 years, provisions to allow CMS to add 3 more years to the provider's or supplier's re-enrollment bar if the provider attempts to re-enroll under a different name, numerical identifier or business identity and provisions to allow CMS to impose a maximum 20 year re-enrollment bar if the provider or supplier is being revoked from Medicare for the second time.

Change in Medicare enrollment regulations

- CMS outlines a 5 year look-back period for reporting previous affiliations. Affiliations are defined as follows:
 - A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
 - A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
 - An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization, either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.
 - An interest in which an individual is acting as an officer or director of a corporation.
 - Any reassignment relationship under § 424.80.

Change in Medicare enrollment regulations

- Once any affiliations are identified, the provider or supplier must determine if there are any disclosable events to report. Disclosable events are defined as follows:
 - Currently has an uncollected debt to Medicare, Medicaid, or CHIP, regardless of—
 - the amount of the debt;
 - whether the debt is currently being repaid (for example, as part of a repayment plan); or
 - whether the debt is currently being appealed.
 - Has been or is subject to a payment suspension under a federal health care program, regardless of when the payment suspension occurred or was imposed;
 - Has been or is excluded by the OIG from participation in Medicare, Medicaid, or CHIP, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed; or

Change in Medicare enrollment regulations

- Has had its Medicare, Medicaid, or CHIP enrollment denied, revoked or terminated, regardless of—
 - the reason for the denial, revocation, or termination;
 - whether the denial, revocation, or termination is currently being appealed; or
 - when the denial, revocation, or termination occurred or was imposed.
- There is no limit to the look back period for disclosable events, except for uncollected debt.
- If CMS determines a particular affiliation poses an undue risk of fraud, waste or abuse, CMS may deny the provider's or supplier's initial enrollment application or the revoke the provider's or supplier's existing Medicare enrollment(s).

Change in Medicare enrollment regulations

- When reviewing for undue risk of fraud, waste or abuse, CMS will take into consideration the following:
 - The duration of the affiliation
 - Whether the affiliation still exists and if not, how long ago it ended
 - The degree and extent of the affiliation
 - If applicable, the reason for the termination of the affiliation
 - The type of disclosable event
 - When the disclosable event occurred or was imposed
 - Whether the affiliation existed when the disclosable event occurred or was imposed
 - If the disclosable event is an uncollected debt
 - The amount of the debt
 - Whether the affiliated provider or supplier is repaying the debt
 - To whom the debt is owed
 - If a denial, revocation, termination, exclusion, or payment suspension is involved, the reason for the disclosable event
 - Any other evidence that CMS deems relevant to its determination.

Change in Medicare enrollment regulations

- Implementation
 - CMS has decided to adopt a “phased-in” approach to implementing the final rule, beginning with a more targeted approach that will then be expanded following further rulemaking and an assessment of the progress of the phased-in approach.
 - For now, providers and suppliers will not be required to disclose affiliations unless CMS, after performing the research and analysis described earlier and determining that the provider or supplier may have at least one affiliation that includes any of the four disclosable events, specifically requests it to do so.

Change in Medicare enrollment regulations

- Implementation continued
 - For now CMS will be responsible for reviewing whether the disclosure requirement applies to the provider or supplier. However, should CMS find, that it does apply, the provider or supplier in question must then report any and all affiliations, not merely the one(s) on which CMS made its determination.
 - CMS will research and consider data revealed through such sources as, but not limited to: (1) PECOS, (2) other CMS databases and external, non-CMS databases, that could indicate behavior (such as improper billing patterns) of concern.

Change in Medicare enrollment regulations

- Implementation continued
 - Once CMS updates the Form CMS-855 applications to include an affiliation disclosure section, a provider or supplier that may have at least one affiliation involving a disclosable event, as identified by CMS, will be required to report any and all affiliations upon initial enrollment or revalidation, as applicable, when CMS specifically requests such information from the particular provider or supplier.
 - CMS does seek public comment on potential approaches for obtaining affiliation information in terms of timing, mechanism, and priority. After receiving and reviewing these comments, CMS will publish a notice of proposed rulemaking (NPRM) outlining the proposed handling of disclosures and will clarify expectations regarding the level of effort required in securing the relevant affiliation information, including data involving the individuals who reassign their benefits, followed by the issuance of a final rule after consideration of the public comments received.

Change in Medicare enrollment regulations

- Impact on Medicaid & CHIP
 - Each state will select one of two options for the implementation of the affiliation disclosure requirement.
 - Under the first option, disclosures must be submitted by all newly enrolling or revalidating Medicaid and/or CHIP providers that are not enrolled in Medicare.
 - Under the second and more targeted option, disclosures must be submitted only upon request by the state. Specifically, the states that choose this second option will request disclosures from those Medicaid and/or CHIP enrolled providers that are not enrolled in Medicare.
 - States will notify CMS, via a process outlined in future subregulatory guidance, as to which of the two options they are choosing and how to inform necessary stakeholders.

Hospital Comingling/Sharing of Space

- May 5, 2015 presentation by CMS, “Hospital Co-Location”
 - All certified hospital space
 - Must be under hospital’s control 24/7
 - Cannot be “part time” part of hospital and “part time” another hospital, ASC, physician office or any other activity
 - Required to be ‘the hospital’ 24/7, however, outpatient department are not required to be open for business 24/7
 - No comingling of physical space (cannot travel through hospital space to get to another entity (no shared space))
 - Cannot travel through another entity to get to the hospital
 - Cannot “time share” a space (hospital space is hospital space 24/7)

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Fall 2018 - CMS notified the provider community written guidance would be forthcoming related to policies on sharing of space, services and staff with other co-located hospitals and healthcare facilities.
- May 3, 2019 – QSO-19-13-Hospital was released in draft form.
 - Once finalized, the guidance will be manualized as sub-regulatory guidance in the Medicare State Operations Manual to guide survey and certification reviews.
 - A draft of the guidance was shared with the CMS Regional Offices, Accrediting Organizations and State Agencies in advance of release to the public on May 3, 2019.
 - Guidance focuses on the hospital provider type but references impact on other Medicare providers/suppliers. Past CMS sub-regulatory interpretations were very restrictive towards co-location arrangements, but CMS's intent through this guidance is to allow more flexibility for shared space arrangements with a focus on patient health and safety.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- The guidance is for hospitals related to sharing of space, services and staff with other co-located hospitals and healthcare facilities.
 - CMS sought to provide clarity about how CMS and State Agency surveyors will evaluate a hospital's space sharing or contracted staff arrangements with another hospital or healthcare entity when assessing the hospital's compliance with its CoPs.
 - Co-location exists when two hospitals or a hospital and another healthcare entity are located in the same building or on the same campus and share space, staff or services.
 - Contractual arrangements of staff may be acceptable.
 - Sharing of public areas (not shared clinical areas) could be considered permissible.
 - Time block leases for specific periods of use by a hospital and other healthcare entity not included in this draft guidance.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Co-location surveying specifics
 - Hospital may be co-located in its entirety or only certain parts of the hospital may be co-located with other healthcare entities. Examples –
 - One hospital entirely located on another hospital's campus or in the same building as another hospital.
 - Part of one hospital's inpatient services (e.g., at a remote location or satellite) is in another hospital's building or on another hospital's campus.
 - Outpatient department of one hospital is located on the same campus of or in the same building as another hospital or a separately Medicare-certified provider/supplier such as an ambulatory surgical center (ASC), rural health clinic (RHC), federally-qualified health center (FQHC), an IDTF, etc.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Co-location surveying specifics
 - CMS states the guidance is specific to the requirements under the hospital CoPs and does not address the specific location and separateness requirements of any other Medicare-participating entity such as psychiatric hospitals, ASCs, RHCs, IDTFs, etc.
 - Regardless of the situation, when a hospital is in the same location (building or campus) as another hospital or healthcare entity, each entity is responsible for demonstrating separate and independent compliance with the hospital CoPs.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Distinct Space and Shared Space
 - A Medicare-participating hospital is evaluated as a whole for compliance with the CoPs and is required to meet the definition of a hospital at all times.
 - It is expected that the hospital have defined and distinct spaces of operation for which it maintains control at all times (floor plans).
 - Distinct spaces would include clinical spaces designated for patient care and is necessary for the protection of patients including, but not limited to, their right to personal privacy and to receive care in a safe environment, and right to confidentiality of patient records.
 - Co-mingling of patients in a clinical area such as a nursing unit from two co-located entities could pose a risk to the safety of a patient as the entities would have two different infection control plans.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Distinct Space and Shared Space
 - Shared spaces are considered those public spaces and public paths of travel that are utilized by both the hospital and the co-located healthcare entity. Both entities would be individually responsible for compliance with the CoPs in those spaces. Examples include –
 - public lobbies,
 - waiting rooms,
 - reception areas (with separate “check-in” areas and clear signage),
 - public restrooms,
 - staff lounges,
 - elevators,
 - main corridors through non-clinical areas, and
 - main entrances to a building.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Distinct Space and Shared Space
 - A public path of travel is, for example, a main hospital corridor with distinct entrances to departments such as outpatient medical clinics, laboratory, pharmacy, radiology. It is necessary to identify, for the public, which healthcare entity is performing the services in which department.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Distinct Space and Shared Space
 - Clinical space is any non-public space in which patient care occurs.
 - Travel between separate entities utilizing a path through clinical spaces of a hospital by another entity co-located in the same building would not be considered acceptable as it could create patient privacy, security and infection control concerns.
 - Examples of non-public paths of travel –
 - a hallway, corridor or path of travel through an inpatient nursing unit; or
 - a hallway, corridor or path of travel through a clinical hospital department (e.g., outpatient medical clinic, laboratory, pharmacy, imaging services, operating room, post anesthesia care unit, emergency department, etc.).

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Contracted Services
 - A hospital is responsible for providing all of its services in compliance with the hospital CoPs.
 - Services may be provided under contract or arrangement with another co-located hospital or healthcare entity such as laboratory, dietary, pharmacy, maintenance, housekeeping and security services.
 - It is also common for a hospital to obtain food preparation and delivery services under arrangement from the entity in which it is co-located, in addition to utilities such as fire detection and suppression, medical gases, suction, compressed air, and alarm systems such as oxygen alarms.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Staffing Contracts
 - Each Medicare-participating hospital is responsible for independently meeting staffing requirements of the CoPs whether provided directly, under arrangement or contract.
 - When staff are obtained under arrangement from another entity, they must be assigned to work solely for one hospital during a specific shift and cannot “float” between the two hospitals during the same shift, work at one hospital while concurrently being “on-call” at another, and may not be providing services simultaneously.
 - All individuals providing services under contract should receive appropriate education and training in all relevant hospital policies and procedures as do those who are direct employees of the hospital.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- Emergency Services
 - Guidance is directed to hospitals without emergency departments and state policies and procedures must be in place for addressing individuals' emergency care needs 24 hours per day and seven (7) days per week.
 - Policies and procedures should include –
 - identifying when a patient is in distress,
 - how to initiate an emergency response,
 - how to initiate treatment, and
 - recognizing when the patient must be transferred to another facility to receive appropriate treatment.
 - Other guidance set forth within the draft.
 - Hospitals without emergency departments that contract for emergency services with another hospital's emergency department are then considered to provide emergency services and must meet the requirements of EMTALA.

Draft – CMS Guidance for Hospital Co-location with other Hospitals or Healthcare Facilities

- What is next?
 - CMS has suggested in an email to Seim Johnson that they may address in their final guidance time block leasing arrangements between a hospital and another healthcare entity.
 - Co-location questions –
 - Should first be directed to the applicable CMS Regional Office (RO) as each CMS RO has historically responded to questions regarding comingling/sharing of space although differently based on their own interpretations. The written guidance from the CMS Central Office (CO) should create consistency across all CMS regions.
 - If additional clarification is needed, the CMS CO could respond.

PPS hospital claim edits for certain hospital outpatient departments

- MLN Matters SE18002 & SE19007 set forth the following –
 - How OPPS providers that have multiple service locations are to report the locations on their hospital claims of where hospital services are provided under different scenarios.
 - Medicare systems will validate reported service facility locations billed on hospital OPPS claims to ensure services are being provided in a Medicare enrolled location. The validation will be an exact matching based on the information submitted on the Form CMS-855A by the provider and entered into PECOS. Providers must ensure that the claims data matches their provider enrollment information. Claims edits to be implemented in April 2020. Billing and enrollment staffs must be coordinated.

MedPac's recommendation for elimination of "incident to" billing for PAs and NPs

- On June 14, 2019, the Medicare Payment Advisory Committee (MedPAC), an independent congressional agency that advises Congress on issues affecting the Medicare program, recommended Congress eliminate "incident to" billing for advanced practice registered nurses (APRNs) and physician assistants (PAs) and require such practitioners to bill for services under their own NPI.

Changes to Signature & Receipt Dates

- CMS made the following changes to the MPIM, Chapter 15, effective October 1, 2018 regarding the filing date of Medicare enrollment applications and certification statements via Transmittal 824, Change Request 10845, dated September 5, 2018.
 - The contractor shall begin processing both paper and Internet-Based PECOS applications upon receipt and shall develop for missing certification statements and all other missing information including application fee, upon review.
 - A signed certification statement is no longer required for applications to be considered received, but still needs to be submitted for the MAC to process the enrollment.
 - Signatures on paper certification statements are no longer required to be original.
 - Handwritten signatures for Forms CMS-855, CMS-20134, CMS-460 and CMS-588 shall be accepted for paper applications and web-based application submission upload.
 - Contractors can no longer accept paper certification statements for web-based application submissions via mail, fax or email. Instead this must be submitted through PECOS upload functionality.

Revisions to Completion of Paper Applications

- Effective Fall/Winter 2019
 - CMS will no longer accept handwritten CMS enrollment applications
 - All paper applications must be typed using the fill feature option on the CMS enrollment forms.
 - If any section of a submitted paper enrollment application is handwritten, the MAC will return the entire application and there will be no appeal rights.
 - For some providers and suppliers, effective dates are based on the receipt date of the application; therefore, the effective date can be impacted by this change if an application is returned

Medicare Deactivation Policy Reinstated

- CMS reinstated the below deactivation policy on a system wide basis April 8, 2019.
- Medicare claims not submitted for four (4) consecutive calendar quarters (12 months), unless current policy or regulations specify otherwise for the provider or supplier type.
 - The 12-month time period runs the 1st day of the 1st month without the submission of a claim through the last day of the 12th consecutive month without submitting a claim.
 - These types of deactivations are defined in the MPIM as CMS or contractor issued deactivations and may mean you also have a Medicare repayment situation.

Medicare Deactivation Policy Reinstated

- Per discussion with WPS provider enrollment supervisors, CMS provided a listing to the MACs of provider/suppliers to deactivate.
- The first WPS list was between 100-200 provider/suppliers.
- Notification letters were sent (see sample letter on next slide).

Medicare Deactivation Policy Reinstated

- Sample WPS deactivation letter

WPS GOVERNMENT HEALTH ADMINISTRATORS
Wisconsin Physicians Service Insurance Corporation
 A CMS Medicare Contractor
 1717 W. Broadway | P.O. Box 5787 | Madison, WI 53701-5787

Month dd, yyyy.

Provider or Suppliers Name
 Provider Organization's Corr. Address
 City, State, ZIP

Dear Provider/Supplier:

We have stopped your Medicare billing privileges on month dd, yyyy, due to inactivity. We will not pay any claims after this date.

What record has been deactivated:

Provider Name:
 Provider NPI:
 Provider PTAN:

Reassignments:
 Legal Business Name:
 Tax ID (last 4 digits):
 State:

How to recover your billing privileges:

Reactivate your Medicare enrollment record, through PECOS, cms.hhs.gov, or form CMS-855.

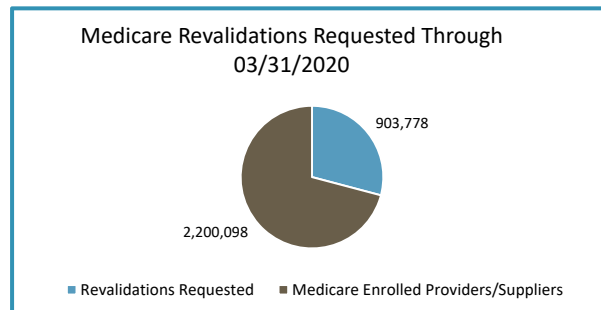
- **Online:** PECOS is the fastest option. If you don't know your username or password, PECOS offers ways to retrieve them. Our customer service can also help you by phone at 866-484-8049.
- **Paper:** Download the right version of form CMS-855 for your situation at cms.gov. We recommend getting proof of receipt for your mailing.

Medicare Deactivation Policy Reinstated

- CMS excludes the following practitioners from this deactivation process if they are employees of Department of Veterans Affairs, Department of Defense, or Public Health Service and employees of Medicare enrolled Federally Qualified Health Center, Critical Access Hospital, and Rural Health Clinic.
 - Doctors of medicine or osteopathy, dental medicine, dental surgery, podiatric medicine, optometry, and chiropractic medicine
 - PAs, NPs, CNSs, CNMs, CPs and CSWs
- Regardless of their employment “pediatric medicine” physicians (specialty 37); and “oral surgery” (dentist only, specialty 19) are excluded from the deactivation process.
- Consider submission of the Form CMS-855O if practitioners will not be billing the Medicare program.

Status of Medicare Cycle 2 Revalidations

- Reminders:
 - All Medicare enrolled providers/suppliers must revalidate every 5 years (DMEPOS suppliers every 3 years)
 - Currently in Cycle 2 mandatory revalidations which started March 2016
- As of September 1, 2019



Update to the Reactivation Policy for Revalidations

- If a provider/supplier misses a revalidation due date, the MAC can apply a pay hold/send a letter of reminder within 25 days after the due date. Sixty to seventy-five days after non-response to a revalidation, the MAC can deactivate the enrollment.
- After deactivation, if the provider/supplier submits an application to reactivate/revalidate its billing privileges:
 - The PTAN will not change
 - There will be a gap in billing between the deactivation date and the date of receipt of the new application. Except for:
 - Certified providers and suppliers, including ASCs and portable x-ray suppliers.
 - A 30 day retrospective billing date is now allowed (see MPIM, Chapter 15, §15.29.4.3). This was a CMS policy change effective as of March 12, 2019.

Changes to IDTF Policies Effective October 7, 2019

- Independent Diagnostic Testing Facilities (IDTF)
 - No longer required to report equipment leased for less than 90 days, unless it results in a new service not already reported.
 - Will now be afforded the ability to change the ownership of an existing IDTF enrollment from one tax-id to another. The effective date of the change of ownership will be the effective date of the IDTF enrollment under the new tax-id (assuming the supporting transactional documents clearly denote the effective date).
 - If MACs are notified that an interpreting or supervising physician no longer provides services at an IDTF, they will request a change of information application be submitted
 - Failure to appropriately update the IDTF enrollment can result in revocation
 - A mobile IDTF permanently fixed to an already enrolled IDTF is no longer required to complete its own separate Medicare enrollment

Q&A

Disclaimer

A presentation can neither promise nor provide a complete review of the myriad of facts, issues, concerns and considerations that impact upon a particular topic. This presentation is general in scope, seeks to provide relevant background, and hopes to assist in the identification of pertinent issues and concerns. The information set forth in this outline is not intended to be, nor shall it be construed or relied upon, as legal advice. Recipients of this information are encouraged to contact their legal counsel for advice and direction on specific matters of concern to them.