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Protect Your Pharmacy's Medicare and Medicaid Enrollment From Termination!

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Medicare Deactivations and Revocations are on the Rise

- As part of an increasing trend from prior years, the Centers for Medicare and Medicaid Services ("CMS") deactivated approximately 123,000 enrollments and revoked 2,290 enrollments in FY 2022.
  - CMS credits **site visits** and **revalidation requests** among the initiatives contributing to deactivations and revocations.
  - More than one million enrollment records have been deactivated or revoked since 2012.
- Regarding some specific enrollment issues, in FY 2022, CMS denied approximately 718 enrollments and revoked 4 enrollments as a result of fingerprint-based criminal background checks or a failure to respond to the request.

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Consequences of Non Compliance for DMEPOS Pharmacies

- Dire consequences for failure to timely and completely respond to enrollment related notices from CMS:
  - Billing privileges may be terminated along with enrollment bars of a minimum of 1 year to a maximum of 10 years.
  - If deactivated – you could have gaps in enrollment status, exposing claims to recoupment.
- As a result, it is critical to understand Medicare enrollment requirements for DMEPOS pharmacies and to ensure your pharmacy remains compliant.

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Medicare Enrollment Requirements

Medicare Enrollment Requirements

DMEPOS pharmacies must meet specific Medicare enrollment requirements to obtain and maintain their billing privileges. These include complying with CMS quality standards and obtaining accreditation from a CMS-approved accreditation organization, unless exempt.

- We will cover supplier standards in greater detail later in this presentation.

- In order to supply Medicare DMEPOS to Medicare patients, suppliers must use the CMS-855S enrollment application form or the Provider, Enrollment, Chain, and Ownership System ("PECOS") for electronic enrollment.
  - The application process involves verifying that the supplier meets all Medicare requirements before granting billing privileges.

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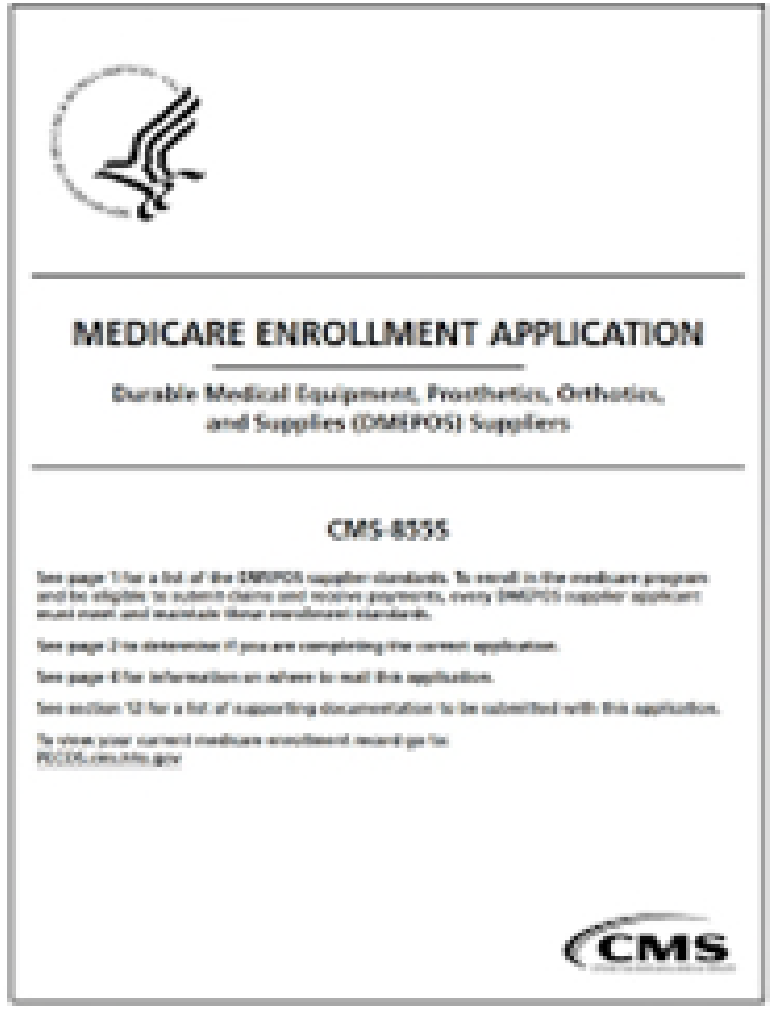
CMS – 855S Form

- Who should use the CMS-855S form?
  - Many different types of DMEPOS suppliers, including Pharmacies, must complete this form to enroll in the Medicare program and receive a Medicare Billing Number
  - This includes suppliers who are new applicants, responding to revalidation requests, reporting changes of information, or for reassignments of benefits
- When using the **paper-based** CMS-855S form, applicants should always ensure they are using the most current version, which can be found within CMS.gov's CMS Forms List at https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms019480



MEDICARE ENROLLMENT APPLICATION

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers

CMS-855S

CMS

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CMS – 855S Form (cont'd)

- Pharmacies can use this form to:
  - Enroll in Medicare for the first time as a DMEPOS supplier
  - Report changes to your current business, (e.g., adding, removing, or changing existing information under a Medicare supplier billing number)
    - changes must be reported within 30 days of the change
  - Enroll a new business location using the same tax identification number ("TIN") already enrolled with the contractor, or for a TIN not currently enrolled
  - Respond to enrollment revalidation requests
  - Reactivate your Medicare DMEPOS supplier billing number
  - Voluntarily terminate your Medicare DMEPOS supplier billing number

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CMS – 855S Form (cont'd)

- Information accuracy – **avoid delays**:
  - Complete and accurate information is required on the application, and any change to existing enrollment data must be reported within 30 days of the effective date of the change.
  - All supporting documentation must be included with the application.
    - Supporting documentation can include documents such as a certificate of liability insurance, surety bond, and an Electronic Funds Transfer ("EFT") authorization agreement with a voided check or bank letter.
  - New enrollees must complete all the sections of the application.
    - Note: for revalidations, you should **not** submit a revalidation application **until contacted and requested** to do so by the contractor.
  - For changes of information, there are specific sections that must be completed depending on the type of change (e.g., new location, ownership, insurance).
  - It is important to ensure the Legal Business Name ("LBN") and TIN match exactly in both PECOS and the National Plan and Provider Enumeration System ("NPPES").
    - The name should also match the bank account name used for EFT funds and any IRS documentation listing the business name.

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CMS – 855S Form (cont'd)

- The CMS-855S form is essential for enrolling in Medicare as a DMEPOS supplier.
  - It collects comprehensive information about the supplier, such as organizational structure, ownership, practice locations, and compliance with supplier standards.
- The form also requires pharmacies to provide financial data and evidence of compliance with applicable federal and state regulations.

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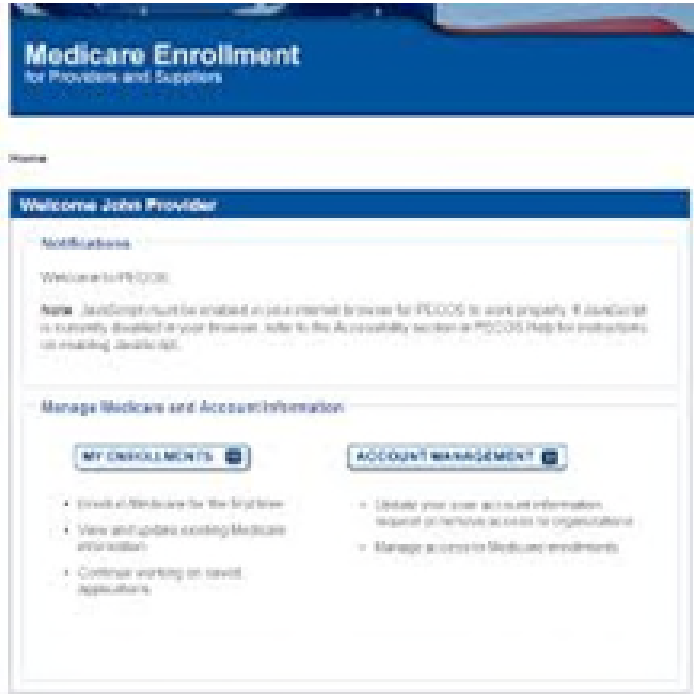
PECOS

PECOS is CMS's online enrollment management system, allowing registered users to securely and electronically submit and manage Medicare enrollment information.



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PECOS (cont'd)

Differences between **PECOS** and **paper** applications:

- PECOS applications are processed more quickly than paper applications.
- Because PECOS is paperless, you would not be required to submit anything by mail.
- PECOS is tailored to ensure that you only supply information that is relevant to your application.
- The PECOS system has video and print tutorials to get you started.
- You can easily check the history of form submissions and enrollment status through PECOS.
- Paper remains a useful option for those who may not be comfortable the electronic process or who are experiencing technical issues.

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Avoid Delays, Rejections, and Revocations

- Examples of pitfalls and avoiding delays, rejections, and revocations:
  - Choose the correct ownership and business section to use between Section 5 (reporting for organizations) or Section 6 (reporting for individuals).
  - For each individual reported for Section 6A ownership interest and/or managing control information, each individual must have a corresponding Section 6B reported for final adverse legal action history, if any, which means there may be multiple Section 6Bs if you have multiple Section 6As to report included on the CMS-855S.
  - Complete and include a newly signed Section 15 Certification Statement when required, CMS will ask for a newly signed Section 15 along with certain missing or corrected information.
  - Provide all required, unexpired, and correct supporting documentation.
  - Report all managing employees and the correct title for each managing employee (either a W-2 Managing Employee or a Contracted Managing Employee if they are not a W-2 employee).
    - A “managing employee” means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operations of the supplier, either under contract, or through “some other arrangement” regardless of whether they are a W-2 employee.

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Avoid Delays, Rejections, and Revocations (cont'd)

- Accurate and complete submission of the CMS-855S form is critical to obtaining and maintaining Medicare billing privileges.
  - Typically, if the Medicare Administrative Contractor (MAC) (e.g. Novitas Solutions, Palmetto GBA) determines there is missing information on an application such as required data, missing supporting documentation, clarification is needed or a Certification Statement is invalid, the MAC will contact the contact person, Individual Provider, or Authorized/Delegated Official for a development request via letter, fax, or email. Suppliers have 30 days to respond completely and accurately to such requests.
  - The MAC will reject applications if the 30-day period has elapsed without response and it is up to the MAC's discretion to make a second request for development.
    - Beware: the MAC only has to reach out once with all development issues included in one request, and often chooses email, be sure that the contact email on file with CMS is correct and checked regularly.

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Avoid Delays, Rejections, and Revocations (cont'd)

- Responding to development requests related to revalidation:
  - While a non-response to a development request in other scenarios (e.g., supplier voluntarily submits an initial application, or an application to change their information) usually results in a rejection of the application, there are different consequences for non-response in the revalidation context.
    - When the MAC requests a revalidation application, and subsequently sends a development request for missing and/or clarifying information, suppliers only have 30 days to respond completely and accurately to such requests and if not, in this context the MAC has authority to not only reject the application but deactivate the supplier.
      - A new reactivation application will then be required and there may be a gap in enrollment/billing privileges as the reactivation effective date will be the date a successful, correct application is received.

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Requirements for DMEPOS Pharmacies

Supplier Standards

Below is an abbreviated version of the supplier standards, found in 42 CFR 424.57(c) and (d), that every DMEPOS supplier must meet in order to obtain and retain their billing privileges (bolded standards are examples of those that have been repeatedly cited as a basis for revocation, and are easy to miss, submit incorrectly, lapse, or be implemented incorrectly).

1. A supplier must be in compliance with all applicable federal and state licensure and regulatory requirements.
2. **A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the contractor within 30 days.**
3. A supplier must have an authorized individual whose signature is binding sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory or contract with other companies for the purchase of items necessary to fill orders. A supplier cannot contract with any entity that is currently excluded from the Medicare program, any state health care programs, or any other federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.

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Supplier Standards (cont'd)

6. **A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable state law, and repair or replace free of charge Medicare covered items that are under warranty.**
7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. **A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items this insurance must also cover product liability and completed operations.**

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Supplier Standards (cont'd)

11. A supplier is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 C.F.R. section 424.57(c)(11).
12. **A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.**
13. **A supplier must answer questions and respond to complaints of beneficiaries and maintain documentation of such contacts.**
14. **A supplier must maintain and replace at no charge or repair cost either directly or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.**
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.

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Supplier Standards (cont'd)

16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. **A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.**
20. Complaint records must include: the name, address, telephone number and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, and any actions taken to resolve it.

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Supplier Standards (cont'd)

21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.
22. **A supplier must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services for which the supplier is accredited in order for the supplier to receive payment for those specific products and services (unless an exception applies).**
23. A supplier must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. A supplier must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.

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Supplier Standards (cont'd)

26. **A supplier must meet the surety bond requirements specified in 42 C.F.R. section 424.57(d) (unless an exception applies).**
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. section 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act), physical and occupational therapists or DMEPOS suppliers working with custom made orthotics and prosthetics.

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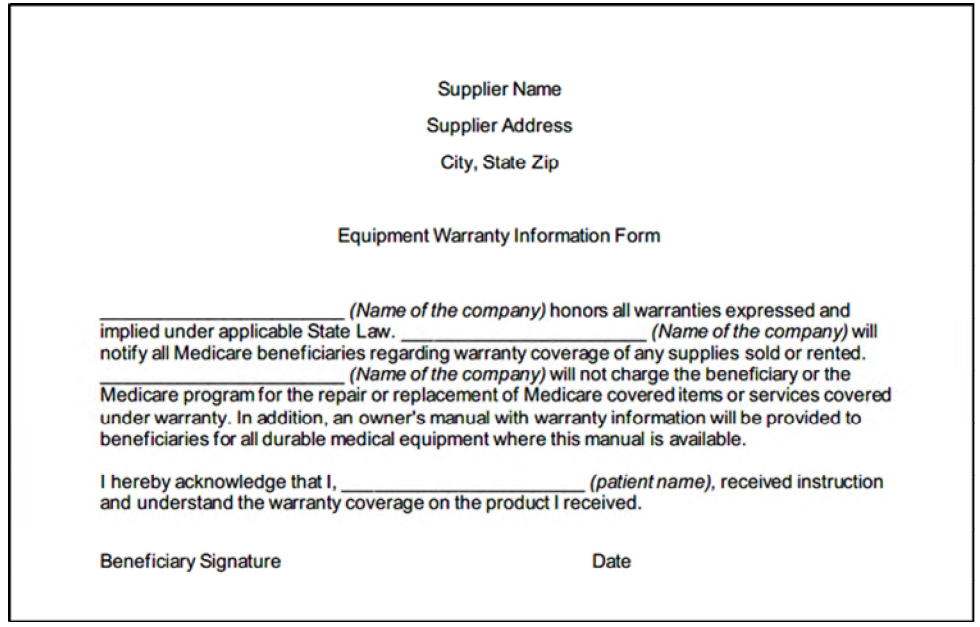
Commonly Cited Standards as a Basis for Revocation

Commonly Cited Standards as a Basis for Revocation

A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable state law, and repair or replace free of charge Medicare covered items that are under warranty. (42 C.F.R. § 424.57(c)(6)).

- The pharmacy should utilize an Equipment Warranty Information Form (this image of a model form is from the MAC Novitas Solutions).
- If applicable, the pharmacy should also be prepared to submit signed forms during an on-site inspection or in a corrective action plan.



Supplier Name

Supplier Address

City, State Zip

Equipment Warranty Information Form

_____ *(Name of the company)* honors all warranties expressed and implied under applicable State Law. _____ *(Name of the company)* will notify all Medicare beneficiaries regarding warranty coverage of any supplies sold or rented. _____ *(Name of the company)* will not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or services covered under warranty. In addition, an owner's manual with warranty information will be provided to beneficiaries for all durable medical equipment where this manual is available.

I hereby acknowledge that I, _____ *(patient name)*, received instruction and understand the warranty coverage on the product I received.

Beneficiary Signature Date

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Commonly Cited Standards as a Basis for Revocation

- **A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items this insurance must also cover product liability and completed operations. (42 C.F.R. § 424.57(c)(10)).**
  - When submitting enrollment and revalidation applications, the CMS-855S form instructs suppliers to include a copy of the Certificate of Liability for its comprehensive (general) liability policy (or evidence of self-insurance).
    - The contractor name, along with full mailing address, must be listed on the policy as a certificate holder.
  - Note: professional and malpractice insurance **is not the same** as comprehensive (general) liability insurance
    - While contractors are instructed by Medicaid Program Integrity guidance to verify insurance with an agent, it is best to follow the CMS-855S instructions and to provide CMS with proper supporting documentation.
  - It is important to promptly respond to revocation letters asserting a lapse in comprehensive liability insurance.
    - E.g., A contractor may send a revocation letter asserting the liability insurance has lapsed, sometimes by mistake for coverage that is still in effect. It is important to respond in a timely manner with the appropriate refuting documentation, and not assume the contractor will eventually verify active coverage on its own to correct its mistake.

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Commonly Cited Standards as a Basis for Revocation

- **A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery (POD) and beneficiary instruction. The supplier must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively. (42 C.F.R. § 424.57(c)(12)).**
  - The contractor may send a revocation letter asserting that the pharmacy did not have POD documentation of items it provided to beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively.
    - Pharmacies should keep samples of its written instructions and information on use and maintenance of items, receipt of items forms, and POD forms, as well as signed copies of such documentation if applicable.
    - Medicare requires POD documentation to be maintained in files for 7 years (starting from the date of service).
      - An example of POD to a beneficiary is having a signed delivery slip, which CMS recommends includes; patient name, quantity, detailed description of item, brand name, serial number, and date of signature on delivery slip must be the date the item was received.

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Commonly Cited Standards as a Basis for Revocation

- **A supplier must answer questions and respond to complaints of beneficiaries and maintain documentation of such contacts. (42 C.F.R. § 424.57(c)(13)).**
- **A supplier must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. (This information must be kept at its physical facility and made available to CMS, upon request). (42 C.F.R. § 424.57(c)(19)).**
  - The pharmacy should utilize a standard Protocol for Resolving Beneficiary Complains form and a Beneficiary Complain Log
  - If applicable, the pharmacy should also be prepared to submit signed forms during an on-site inspection or in a corrective action plan

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Examples of Model Complaint Protocol and Complaint Log Forms From the MAC Novitas Solutions:

Supplier Name

Supplier Address

City, State Zip

Protocol for Resolving Complaints from Medicare Beneficiaries

The patient has the right to freely voice grievances and recommend changes in care of services without fear of reprisal or unreasonable interruption of services. Service, equipment, and billing complaints will be communicated to management and upper management. These complaints will be documented in the Medicare Beneficiaries Complaint Log, and completed forms will include the patient's name, address, telephone number, and health insurance claim number, a summary of the complaint, the date it was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

All complaints will be handled in a professional manner. All logged complaints will be investigated, acted upon, and responded to in writing or by telephone by a manager within a reasonable amount of time after the receipt of the complaint. If there is no satisfactory resolution of the complaint, the next level of management will be notified progressively and up to the president or owner of the company.

The patient will be informed of this complaint resolution protocol at the time of set-up of service.

Supplier Name

Supplier Address

City, State Zip

Medicare Beneficiary Complaint Log

Date of receipt of complaint:

Patient Information

Name:

Address:

City:

State:

Zip:

Telephone number:

Health Insurance Claim Number (HICN):

Description of complaint:

Action taken to resolve the complaint:

Signature of representative Date

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Commonly Cited Standards as a Basis for Revocation

- **A supplier must meet the surety bond requirements specified in 42 C.F.R. section 424.57(d) (unless an exception applies). (42 C.F.R. § 424.57(c)(26)).**
  - A few of these requirements include:
    - Minimum Surety Bond: $50,000 continuous bond required (or an elevated amount if required by CMS due to adverse legal actions)
    - There must be no gap in the coverage of surety bond periods if a supplier cancels and obtains a new bond
    - Term: the term of the initial surety bond must be effective when the application is submitted
      - Note: for changes in ownership, if the bond is effective at a later date, the effective date of the new billing privileges will be the effective date of the surety bond
      - For new locations, suppliers must submit a new surety bond or an amendment to the existing bond
    - It is important to promptly respond to revocation letters asserting a failure to maintain a valid surety bond
      - E.g., A contractor may send a revocation letter asserting a failure to maintain a valid surety bond and that the bond has lapsed, sometimes by mistake for coverage that is still in effect. It is important to respond timely with the appropriate refuting documentation.

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Commonly Cited Standards as a Basis for Revocation

- **A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the contractor within 30 days. (42 C.F.R. § 424.57 (c)(2)).**
  - Beware of significant changes to report, which may include a change in ownership, an adverse legal action, or a change in practice location, however, in order to avoid revocation, CMS cautions suppliers to be sure to report ***any*** change within 30 days.
    - Example: Changes to application under 42 C.F.R. § 424.57(c)(2) and new product lines requiring accreditation under 42 C.F.R. § 424.57(c)(25)
      - CMS may assert a failure to provide notification of changes in the pharmacy's rendering accredited products and services.
        - It is important to be sure that all staff are aware of billing procedures for particular DME, especially if the pharmacy does not have an exemption from accreditation, and if particular DME are not indicated on the pharmacy's enrollment application list of rendering products and services. (E.g. a pharmacy is not yet qualified as exempt from accreditation and bills blood glucose monitors/supplies which are not indicated on the rendering products and services).

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Commonly Cited Standards as a Basis for Revocation

- **A supplier must maintain and replace at no charge or repair cost either directly or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries. (42 C.F.R. § 424.57(c)(14)).**

  - Pharmacies should keep protocol forms on file in order to document maintenance, replacement and repair, and be prepared to submit records of documentation if maintenance, repairs, or exchanges have occurred

    - Note: these requirements relate to Medicare-covered items ***rented*** to beneficiaries

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Accreditation Requirements and Exemptions

Accreditation Requirements and Exemptions

- To supply Medicare DMEPOS, suppliers must be accredited by a CMS-approved independent national accreditation organization, which ensures compliance with CMS quality standards.
- Certain pharmacies can be exempt from accreditation if they meet specific criteria, such as having been enrolled in Medicare as a DMEPOS supplier for at least five years, and maintaining DMEPOS billing below 5% of total pharmacy sales for the previous 3 calendar or fiscal years.
  - What does CMS mean by “pharmacy sales” for exemption?
    - Those that are in a separate pharmacy account(s) for entities whose accounting system has such a breakout; or
    - For pharmacies without such breakouts of pharmacy items versus non-pharmacy items (usually small pharmacies) the total gross sales of the pharmacy.

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Exemption Criteria

- In the accreditation exemption statement, Pharmacies attest they meet the following criteria:
  - The pharmacy has been enrolled in Medicare as a DMEPOS supplier for at least 5 years;
  - The pharmacy has not had an unrescinded final adverse action during the past 5 years;
  - The pharmacy's Medicare billing for DMEPOS (other than drugs and pharmaceuticals which are not subject to accreditation) is less than 5% of their total pharmacy sales over the previous 3 calendar or fiscal years; and
  - The exemption attestation must be signed by the Authorized or Delegated Official on the CMS-855S enrollment application.

- Pharmacies that are ineligible for accreditation exemption include new pharmacy chains and independent locations (due to the 5 year enrollment issue) and those with changed ownership, changed legal business entity, or those that received a different Taxpayer Identification Number in the past 5 years.

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Avoid Revocation

- If the pharmacy has more than one practice location, each individually enrolled location must submit a separate attestation for exemption:
  - New locations of enrolled multiple-location pharmacies are not considered enrolled for the necessary 5 year enrollment minimum
  - Pharmacies that have had a change of ownership in the prior 5 years resulting in a change to their legal business entity, including a change in their Taxpayer Identification Number also do not quality for exemption
  - If the pharmacy is no longer accredited and does not qualify for exemption, Medicare billing privileges will be revoked
  - If the pharmacy no longer meets the pharmacy sales criteria or has experienced a final adverse action, then the pharmacy will be immediately subject to the accreditation requirement of 42 C.F.R. 424.57(c)(22)
    - If this occurs, the pharmacy agrees (by signing the exemption attestation) to notify their Medicare contractor in writing within 30 days of the date it no longer met these requirements
  - During an audit, the pharmacy should be prepared to submit materials to verify that it meets the criteria such as a certification by an accountant on behalf of the pharmacy or the submission of tax returns during the relevant periods.

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Common Reasons for Non-Compliance

Common Reasons for Non-Compliance

- Non-compliance can result from various issues such as failing to meet supplier standards, not reporting changes in ownership or practice locations, and failing to respond to revalidation requests.
  - Other examples include failure to maintain a valid state license or report adverse legal actions
  - Providers must regularly review their compliance status and address any potential issues promptly to avoid penalties.
- Failure to timely respond to development requests for missing information and documentation, or information requiring clarification can result in deactivation
  - Note: development requests from the contractor may only come through one form of communication, such as one email to the email address on file in a supplier's application, serving as notice to the supplier, which much be answered within 30 days.

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Billing Privileges

Deactivation of Billing Privileges

- Medicare can deactivate a provider's billing privileges if they
  - fail to submit claims for 6 consecutive months,
  - do not respond to revalidation requests (and fail to respond to development requests), or
  - fail to report changes in their enrollment information such as a change of the practice location, managing employee or a change in ownership within 30 days.
- Deactivation is essentially a "pause" in billing privileges, and providers must submit a new CMS 855S application to reactivate their billing privileges.
  - Pharmacies may be able to argue there should be no lapse or “pause” in billing privileges, through a rebuttal procedure set forth in the deactivation letter, which must be submitted within 15 calendar days of the date of the deactivation letter.
    - Note: If a development request is received, it may be helpful to contact the enrollment specialist assigned to the request (if their contact is provided) for more information related to the requests, in order to submit the appropriate responsive information in time to try to avoid pauses, confusion, and deactivation (and subsequently, use of the rebuttal procedure)

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Deactivation of Billing Privileges

- The effective date of reactivation is typically based on the receipt date of the application.
- For deactivations under 42 CFR 424.540(a)(4) (which means the provider or supplier was not compliant with all enrollment requirements in the title), a provider has the opportunity to submit a rebuttal where the contractor will review all submitted documentation and internal records to determine whether the provider was in fact compliant with all enrollment requirements at the time of deactivation. If so, then the contractor should approve the rebuttal request and reinstate the provider's billing privileges to an approved status.
  - Note: It is important to include the best form of contact on enrollment applications (and keep updated when necessary) to help mitigate potential contact issues.
  - Retroactive deactivation could lead to significant financial recoupment.

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Revocation of Billing Privileges

- Billing privileges can be revoked for several reasons, including non-compliance with enrollment requirements, not meeting the Medicare supplier standards, or being excluded from federal health care programs.
- Revocation results in the termination of the provider agreement and imposes a re-enrollment bar of 1 to 3 years.
  - When rebuttals, corrective action plans and reconsideration requests are allowed, it is important to note these options and deadlines.
    - Rebuttals to deactivations must be received within 15 calendar days
    - Corrective action plans must be received within 35 calendar days
    - Reconsideration requests must be received within 65 calendar days
      - Note: CMS may not send correction action plan determination to the pharmacy until after the reconsideration request deadline has passed

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Appeals Process

Appeals Process Overview: CAPs and Reconsideration Requests

The appeals process allows providers to contest adverse determinations such as denials or revocations of Medicare billing privileges. The process includes submitting Corrective Action Plans (CAPs), reconsideration requests, and pursuing hearings with an Administrative Law Judge (ALJ).

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Appeals Process Overview: CAPs and Reconsideration Requests

- CAPs must:
  - Contain verifiable evidence that the provider/supplier is in compliance with Medicare requirements;
  - Be submitted within 35 days from the date of the denial or revocation notice;
  - Be submitted in the form of a letter that is signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative.
  - If a legal representative is an attorney, the CAP must also contain a statement that the attorney has the authority to act on behalf of the provider/supplier. If the legal representative is not an attorney, the CAP must contain written notice of the appointment of the non-attorney as legal representative signed by the provider, supplier, or authorized/delegated official.
  - A decision should be issued within 60 days of receipt of the CAP.

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Appeals Process Overview: CAPs and Reconsideration Requests

- Reconsideration Requests must:
  - State the issues, or the findings of fact with which you disagree, and the reasons for disagreement.
  - Be submitted within 65 days from the date of the initial determination;
  - Be submitted in the form of a letter that is signed and dated by the individual provider/supplier, the authorized or delegated official, or a legal representative.
  - If a legal representative is an attorney, the reconsideration request must also contain a statement that the attorney has the authority to act on behalf of the provider/supplier. If the legal representative is not an attorney, the reconsideration request must contain written notice of the appointment of the non-attorney as legal representative signed by the provider, supplier, or authorized/delegated official.
  - A decision will be issued within 90 days of receipt of the reconsideration request.

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Administrative Law Judge (ALJ) Hearings

- Providers who are dissatisfied with the outcome of a reconsideration request can request a hearing before an Administrative Law Judge (ALJ). This hearing provides an opportunity to present evidence and arguments in person.

- The request for an ALJ hearing must be filed within 60 days of the reconsideration decision. Providers should prepare thoroughly for the hearing, presenting all relevant evidence and legal arguments to support their case.

- If the request was not filed within 60 days the provider may file with the ALJ a written request for extension of time stating the reasons why the request was not filed timely. The ALJ may extend the time for filing the request for hearing if good cause is shown.

- The ALJ must issue a written decision, dismissal order, or remand to CMS.

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Departmental Appeals Board (DAB) Reviews

- If the provider disagrees with the ALJ's decision, they can request a review by the Departmental Appeals Board (DAB).
  - This request must be filed within 60 days of the receipt of the notice of the ALJ decision or dismissal, unless the Board extends time for filing good cause.
- The DAB review focuses on whether the ALJ's decision was based on substantial evidence and in accordance with the law.
- Providers should ensure that all relevant evidence and arguments are included in the review request.

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Judicial Reviews

- Judicial reviews involve seeking a review of the DAB's decision by a federal court.
  - This step is typically the final stage in the appeals process.

- Providers must file a civil action in federal district court within 60 days of receiving the DAB's decision.
  - It can be very valuable to have legal representation during this stage to navigate the complexities of federal court procedures.

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Site Visit Requirements

- Site visits are conducted to verify compliance with Medicare enrollment requirements and supplier standards.
  - These visits are mandatory for high-risk providers, such as DMEPOS suppliers, during initial enrollment, revalidation, and when adding new locations.
    - When CMS designates a provider or supplier as a “high” categorical level of risk, the Medicare contractor performs all of the following: (i) Performs the “limited” and “moderate” screening and (ii) (A) Requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and (B) Conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

- CMS has the authority to perform unannounced site visits to ensure that providers meet all enrollment and operational standards.
  - Providers should be prepared for these visits by maintaining accurate and up-to-date records.

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Role of National Site Visit Contractors (NSVCs)

- National Site Visit Contractors (NSVCs) are responsible for conducting site visits on behalf of CMS.
  - They perform both external and internal reviews during unannounced visits conducted during normal business hours

- NSVCs verify practice location information, perform staff interviews, assess inventory, and review documentation such as complaint logs, warranty information, and rental/purchase agreements.
  - Site visits can be very quick, providers should ensure that all required documentation is readily available.

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Administrative Actions Based on Site Visit Findings

- Based on site visit findings, CMS can take various administrative actions, including revocation of billing privileges, deactivation of billing privileges, and imposing Corrective Action Plans (CAPs).

- Common issues leading to administrative actions include non-operational practice locations, unreported changes in practice locations, and failure to maintain supplier standards.
  - Providers should address any deficiencies identified during site visits promptly.

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Medicaid Revocation

Collateral Effect

- Pharmacies that do not have or maintain CMS-855S enrollment where required do not meet New York Medicaid enrollment criteria and therefore may not be enrolled, or may be dis-enrolled, from Medicaid.
  - Examples of pharmacy types that require 855S enrollment:
    - Closed-door long-term care pharmacies
    - Open-door community pharmacies with immunization services
    - Open-door community pharmacies with practitioner administered drugs
    - Closed-door infusion pharmacies and closed-door specialty pharmacies (mail order, limited distribution drug, high-cost drugs, special handling drugs)
      - These pharmacy types situationally require 855S enrollment, depending on whether the pharmacy carries one or more items that would be required to be billed to Medicare on behalf of a dual-eligible member

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Compliance Tips

- Regularly review and update all enrollment information to ensure accuracy.
  - This includes verifying ownership details, practice locations, and any changes in the organization's structure.
- Conduct internal audits to identify and address potential compliance issues before they become significant problems.
- Monitor all CMS and Medicaid communications closely, making sure that contact information on enrollment forms is up to date and a preferred form of contact (if email, includes checking spam folders especially with regard to application development requests which are frequently emailed)
- Respond to and be aware of development, rebuttal, corrective action plan, and reconsideration request deadlines to allow enough time to prepare a response
- Train staff on Medicare requirements and the importance of maintaining accurate records.
- Utilize development request contact information if a specific enrollment specialist is listed

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Questions?

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Robert Del Giorno is the Chair of Garfunkel Wild's Investigations, Audits and Regulatory Compliance Practice Group. Robert's practice includes representation of skilled nursing facilities, laboratories, physicians and other health care industry-related clients (both for profit and not-for-profit) in the area of health care compliance, with a specific focus on fraud and abuse laws. He has particular expertise assisting clients with internal investigations and frequently defends clients in both civil and criminal investigations conducted by federal and state agencies. Robert has defended local New York hospitals and individual providers in complex, multi-million dollar Federal and New York State False Claims Act cases and has handled a wide variety of other high-profile matters. Robert also represents clients in the health care and early intervention industries with regard to audits conducted by government agencies.

In addition, Robert frequently assists clients in developing effective compliance programs, working with them to develop and implement policies tailored to meet their individual needs.

Robert frequently consults on a variety of business transactions and arrangements, including asset purchases, financing and factoring agreements, among others. In this regard, Robert conducts due diligence reviews of health care providers in order to help clients identify and understand potential health care compliance risks and liabilities.

Robert started his career with a large corporate law firm in New York City, where he focused on commercial litigation and criminal defense matters. Prior to joining the firm, Robert served as an Assistant District Attorney in the Nassau County District Attorney's Office where he tried numerous cases to verdict. As a member of the Special Victims Bureau, he handled cases involving victims of sex crimes and domestic violence. Many of Robert's cases and trials were covered by the media, including his trial of a man featured on America's Most Wanted.

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Andrew Ko joined Garfunkel Wild, P.C. in 2021. Andrew represents various healthcare providers on regulatory and transactional matters. He has represented providers with challenging audits conducted by the New York State Office of the Medicaid Inspector General (OMIG), the Office for People with Developmental Disabilities (OPWDD), and Centers for Medicare & Medicaid Services (CMS). During this representation, he has contested the statistical sampling and extrapolation methodology implemented to calculate the purported overpayments. He has also counseled clients on regulatory compliance issues, government investigations, and self-disclosures.

Prior to joining the firm, Andrew worked as a health law associate for a regional law firm. He also was an Appellate Court Attorney at the State of New York Supreme Court, Appellate Division, Third Judicial Department, where he conducted legal research and drafted preliminary reports for the Court. While in law school, Andrew was a judicial extern for Hon. Christian F. Hummel in the United States District Court, Northern District of New York, interned for the Claims Bureau at the Office of the Attorney General, and interned for the Innovations and Partnership group at the Research Foundation for the State University of New York.

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Vanessa Giunta joined Garfunkel Wild, P.C. in 2022. She works on regulatory, corporate, and transactional matters for clients including, but not limited to, hospitals, medical providers, ambulatory care facilities, physician practices, and other for-profit and not-for-profit entities. Vanessa also has experience working on clinical trial and grant award agreements with research sponsors.

Prior to joining the firm, Vanessa was a Public Health Law Program Legal Intern at the Centers for Disease Control and Prevention, a Research Fellow at the Gitenstein Institute for Health Law and Policy, and a Clinic Intern at the Robert W. Entenmann Veterans Law Clinic. Vanessa was also a Certified Pharmacy Technician at local pharmacy companies and a Director of Reimbursement for a long term care pharmacy.

While in law school, Vanessa had her Note published in the Hofstra Labor & Employment Law Journal and received the highest level of Hofstra Law's Public Service Awards for completing over 750 hours of public service work.

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