Heightened Scrutiny with Grave Consequences

Navigating the Maze of
Medicare and Medicaid Enrollment Requirements
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Topics to Cover

- Enhanced Program Integrity safeguards -- new Medicare and Medicaid enrollment rules effective 3/25/2011.
- Requirements to maintain accurate and complete enrollment data on file and overview of sanctions for failing to do so.
- Strategies to avoid a failed site verification visit, billing privilege deactivation or revocation.
- Common errors in application submissions and tips for completing enrollment forms.



Enhanced Program Integrity Safeguards

Required by Patient Protection and Affordable Care Act



42 C.F.R. § 424.518

- CMS established three categories of providers and suppliers based on perceived risk of fraud:
 - Limited Risk,
 - Moderate Risk, or
 - High Risk
- More rigorous enrollment screening procedures as the perceived risk increases.



TABLE 1—CATEGORY OF RISK AND REQUIRED SCREENING FOR MEDICARE PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, PROVIDERS, AND SUPPLIERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicare	X	×	X
ficial, or supervising physician)	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Criminal Background Check			X
Fingerprinting			X



Table 6. Final Medicare Providers and Suppliers Categories Designated to the "Limited" Level for Screening Purposes

Provider/Supplier Category

Physician or non-physician practitioners and medical groups or clinics, with the exception of physical therapists and physical therapist groups

Ambulatory surgical centers, competitive acquisition program/Part B vendors, end-stage renal disease facilities, Federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, mass immunization roster billers, organ procurement organizations, pharmacies newly enrolling or revalidating via the CMS-855B, radiation therapy centers, religious non-medical health care institutions, rural health clinics, , and skilled nursing facilities.



Table 7. Final Medicare Providers and Suppliers Categories Designated to the "Moderate" Level for Screening Purposes

Provider/Supplier Category

Ambulance suppliers, community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities; independent clinical laboratories; physical therapy including physical therapy groups and portable x-ray suppliers.

Currently enrolled (revalidating) home health agencies.

Table 8. Final Medicare Providers and Suppliers Categories Designated to the "High" Level for Screening Purposes

Provider/Supplier Category

Prospective (newly enrolling) home health agencies and prospective (newly enrolling) suppliers of DMEPOS..



- Individual provider or supplier can be moved to high-risk category:
 - Provider or supplier had exclusion, billing privilege revocation or termination or was others precluded from billing Medicare.
 - Provider or supplier had payment suspension imposed.
 - Provider or supplier had final adverse action.
 - For first 6 months following enrollment moratorium.



Licensure and Database Checks

- <u>Licensure</u> -- State licensing data:
 - Verify still in effect, correct location, any sanctions imposed.
 - When: initial enrollment, on monthly basis, revalidation.
- <u>Database</u> --initial enrollment, some monthly, revalidation:
 - Check all names against OIG List of Excluded Parties and the GSA Debarment List.
 - All SS#s matched against the SSA's database. Contactors receive monthly file of deceased individuals from SSA.
 - The provider's legal name and tax identification number verified via the submission of the IRS documentation.
 - The CMS 855 data is compared to NPI data.
 - NPDB no procedures in place yet to verify NPDB information.



- June 2006 enrollment regulation changes authorized CMS to conduct on-site reviews to determine if "operational." Site verification visits differs from surveys and inspections to determine compliance with conditions of participation and supplier standards.
- Final 2011 enrollment regulations:
 - CMS noted it already had authority to "conduct ad hoc pre- and post enrollment site visits to any prospective ... or any enrolled Medicare provider or supplier."
 - Although primary purpose is to determine if "operational" the "contractor may also verify established supplier standards or performance standards" to ensure "compliance with program requirements."



- PIM CMS Pub. 100-08, Ch. 15 § 19.2.2 [Determination of operational for all but DMEPOS suppliers and IDTFs.]
- Contractor shall determine whether the following criteria are met:
 - The facility is open.
 - Personnel are at the facility.
 - Customers are at the facility (if applicable to that provider or supplier type).
 - The facility appears to be operational.



- Operational means the provider or supplier [PIM CMS Pub. 100-08, Ch. 15 § 1.1]:
 - Has a qualified physical practice location,
 - Is open to the public for the purpose of providing health care related services,
 - Is prepared to submit valid Medicare claims; and
 - Is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, supplier specialty, or the services or items being rendered) to furnish these items or services.



Additional Rules for <u>DMEPOS</u> Suppliers -- Effective 9/27/10 generally require:

- Operational practice location -- minimum of 200 square feet.
- Permanent, durable sign which is visible at the main entrance and identifies the DMEPOS supplier.
- Open to public minimum 30 hours/week --CMS 855S form changed to require reporting days & hours of operation.



Additional Rules for IDTF Suppliers:

- Be accessible during regular business hours to CMS and beneficiaries; and
- Maintain a visible sign posting its normal business hours.



CMS Guidance for providers and non-DMEPOS/IDTF suppliers (PIM CMS Pub. 100-08, Ch. 15 § 20):

- Should be done Monday Friday (excluding holidays) during:
 - The provider or supplier's posted business hours, or
 - If no hours posted, then between 9 a.m. and 5 p.m.
- <u>First attempt</u>: If obvious signs that facility or practice location is no longer operational, then no second attempt is required.
- If facility or practice locations is closed but no obvious indications it is non-operational, then make a <u>second</u> <u>attempted</u> site visit on a different day during the posted hours of operation.



- Inspectors conducting site visits required to:
 - Document the date and time of the attempted visit.
 - Take photographs of the business as appropriate.
 Date and time stamp the photographs.
 - Fully document observations made facility vacant, eviction notice, space occupied by another provider or supplier.
 - Write a report of findings.
 - Sign a declaration stating the facts and verifying the completion of the site visit.



- For DMEPOS Suppliers:
 - CMS instructs the NSC to continue to conduct onsite inspections consistent with NSC's Statement of Work.
- For IDTF Suppliers:
 - Performed via use of CMS 10221 form.
 - For mobile IDTF:
 - Mobile unit may visit the office of the site reviewer, or
 - The site reviewer may obtain an advance schedule of the locations the IDTF will be visiting and conduct the site visit at one of those locations.



Timing of Site Verification Visits

- For Initial Enrollment:
 - For certified providers and certified suppliers: after contractor receives the tie-in notice but prior to conveying billing privileges.
 - For non-certified suppliers: prior to the contractor's final decision regarding enrollment.



Timing of Site Verification Visits

- For new Practice Locations :
 - For certified providers and certified suppliers: prior to contractor making recommendation for approval.
 - For non-certified suppliers: prior to contractor's final decision regarding the application.
- For Revalidations:
 - Prior to contractor's final decision regarding the revalidation application.



- Required actions for failed site verification visit:
 - In <u>new enrollee</u>: must deny enrollment.
 - If <u>existing provider or supplier</u>:
 - Must revoke billing privileges within seven (7) calendar days of CMS' or the Medicare contractor's determination or noncompliance.
 - Effective date of revocation is date found to be out of compliance.



- Steps to take to avoid a revocation action based on an unsuccessful site visit:
 - Confirm that current and complete data regarding practice location is on file.
 - Timely report any change in business name, address, hours of operation.
 - Ensure that existing signage is accurate, including posted hours of operation.
 - Update enrollment data to include information that would be necessary to find the practice location.



- Concerns with Site Verification Visit policy:
 - <u>Site Visits</u>: no procedural safeguards to protect legitimately operating business:
 - Inspector fails to gain access during hours of operation -- could require inspector to call provider or supplier to notify of attempted visit.
 - Contractor's failure to have entered current address in PECOS database in response to revalidation or change of information filing -could require temporary deactivation with opportunity to prove compliance with requirements.



Criminal Background Checks and Fingerprint Screening

- Individuals with a 5% or more direct or indirect ownership interest.
 - Must submit fingerprints for national background check.
 - When: in conjunction with submission of enrollment application <u>and</u> within 30 days of request by contractor to do so.

NOTE: Only provision in final rules that did not become effective 3/25/2011.



Criminal Background Checks and Fingerprint Screening

- Cost of fingerprinting will be the responsibility of individual.
- CMS will bear cost of conducting the criminal history record check.
- To help deter expenses:
 - Medicaid agencies can rely upon Medicare contractor screening.
 - Medicaid agencies can rely upon results of other state Medicaid screenings.



- Enrollment and Revalidation Application Fees for all "institutional" providers (42 C.F.R. § 424.514):
 - Includes all providers and suppliers that submit CMS 855A, CMS 855B or CMS 855S form except physician or practitioner groups.
 - Amount is \$505 for 2011 with annual update.
 - Paid electronically through <u>www.Pay.gov</u> via credit card, debit card, or check.
 - CMS will regularly send a listing of providers and suppliers (the "Fee Submitter List") that have paid an application fee to contractors.
 - However, recommend sending payment receipt with application.
 - May request "hardship" exception.



- Temporary Moratoria (42 C.F.R. § 424.570):
 - Imposed in 6-month increments where --
 - CMS determines there is a signification potential for fraud, waste or abuse, such as
 - Highly disproportionate # providers/suppliers to beneficiaries,
 - Rapid increase in enrollment applications within category.
 - A State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider of supplier type or both.
 - CMS, in consultation with OIG or DOJ identifies either or both of the following as having a significant potential for fraud, waste or abuse:
 - A particular provider or supplier type.
 - Any particular geographic area.
 - Will announce moratoria via Federal Register with rationale.



Temporary Moratoria (Continued):

- Moratoria will be limited to:
 - Newly enrolling providers and suppliers (i.e., initial enrollment applications); and
 - Establishment of new practice locations, <u>not</u> a relocation of an existing practice location.
- Moratoria would not apply to existing providers or suppliers of services <u>unless</u>:
 - Attempting to expand operations to new practice locations where a temporary moratorium was imposed.
- Moratoria would not apply to changes in ownership of existing providers or suppliers, mergers, or consolidations except:
 - Home health agencies affected by the 36-month rule.
- CMS will deny enrollment applications received from providers or suppliers covered by an existing moratorium.



- Suspension of Payments (42 C.F.R. §§ 405.370 and 405.371):
 - During an investigation of a "credible allegation of fraud" i.e., from a reliable source with an "indicia of reliability."
 - Sets an 18-month time limit for the payment suspension except in certain specific situations.



- Requirement for Medicaid revalidations (42 C.F.R. § 455.414):
 - Medicaid revalidation every 5 years.
 - CMS expects first revalidation cycle to be completed by 2015, with 20% revalidating each year beginning in 2011.
- Requirement for Medicaid terminations (42 C.F.R. § 455.416):
 - Mandatory termination for certain reasons including failing to comply with screening, Medicare or other state Medicaid termination.
 - Permissive termination reasons included.



Medicaid Enrollment Screening 42 C.F.R. §§ 455.410 and 455.450

- State must enroll all ordering or referring physicians or other professionals rendering Medicaid services.
- Must identify limited, moderate, and high risk categories of providers with similar screening requirements for each category.
- Identifies specific situations in which the State must adjust the risk category.
- Timing of screening is the same: initial, new practice location, and re-enrollment or revalidation.



Requirements to Maintain Current Enrollment Data

Medicare Revalidation

Revalidation: every 5 yrs. except DMEPOS (3 yrs.):

- <u>Timing</u> of Revalidation:
 - Within 60 days of contractor's request to do so.
 - May voluntarily revalidate at any time.
- <u>Process</u>: Contractor sends request to revalidate -may be sent to practice location <u>not</u> the correspondence address.
- Failure to respond to request to revalidate will result in billing privilege revocation.

NOTE: Revalidation <u>does not negate</u> the need to timely report changes in enrollment data.



- All providers and suppliers have <u>30 days</u> from the effective date to report a change <u>Ownership or Control</u>:
 - Includes any changes in individuals or entities with 5% or more direct or indirect ownership interest.
 - Includes any change in an officer, governing body member, authorized official, delegated official, management company, or managing employee.



• Final adverse actions:

- Physicians and practitioners, individuals and groups, DMEPOS suppliers and IDTFs have 30 days to report.
- Air ambulance suppliers have 30 days to report the revocation or suspension of a federal or state license or certification, including FAA certifications.
- Other suppliers and providers have 90 days to report.



- Request to <u>add new practice location</u>:
 - Certified providers and certified suppliers: advance reporting requirement:
 - Prior approval required.
 - State survey agency may or may not conduct survey to determine compliance with conditions of participation.
 - Approval by Regional Office with issuance of tie-in notice.
 - Non-certified suppliers: generally have 90 days to report the new location with the exception of:
 - Physicians and nonphysician practitioners, individuals and groups: 30 days to report change.
- Relocation of existing practice location:
 - Generally, 90 days to report change.
 - DMEPOS and IDTF suppliers: 30 days to report change.



- Other changes generally need to be reported within 90 days following the change with the exception of:
 - DMEPOS Suppliers: only have 30 days to report <u>any</u> change in enrollment data.
 - IDTF Suppliers: only have 30 days to report a change in general supervision.



Increasing Sanctions for Failing to Comply

Enforcement Efforts Increasing

- Effective <u>June 2006</u>: Change in regulations to allow the imposition of sanctions for failing to provide timely updates:
 - Deactivation of billing privileges.
 - Revocation of billing privileges.
- Effective <u>August 2008</u>: Implemented a one- to three-year bar to Medicare re-enrollment following a revocation.
- Effective <u>January 2009</u>: Change to authorize CMS to initiate certain <u>overpayment actions</u> for services provided from the date of the reportable event.
- Effective <u>September 2010</u>: Change to authorize CMS to initiate <u>overpayment actions</u> for DMEPOS supplier from date of final adverse action.



- Deactivation -- temporary suspension of billing privileges without termination of the supplier agreement.
 - May need to submit new CMS 855 form to obtain reactivation.
 - Potential issue with effective date of reactivation.
- Revocation -- automatic termination of the supplier agreement:
 - Generally, effective 30 days following notice.
 - Exception if based on final adverse action, then effective date of the action.
 - Becomes reportable event Medicare,
 Medicaid and other third party payers, licensing
 agencies.
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The letter revoking billing privileges must contain:

- A legal basis for each reason for revocation;
- A clear explanation including the facts or evidence used by the contractor in making the revocation determination;
- An explanation of why the enrollment criteria or program requirement were not satisfied;
- The effective date of the revocation;
- Procedures for submitting a Corrective Action Plan (CAP); and
- Complete and accurate information about further appeal rights.



Corrective Action Plan:

- Process to give the provider or supplier an opportunity to correct the deficiencies (if possible) that resulted in the revocation.
- Should provide evidence that the provider or supplier is in compliance with Medicare requirements.
- Contractors should inform providers and suppliers that submission of a CAP will expedite the process and issue a faster determination
- CAP must be submitted within 30 days from the date of the notice of the revocation.



Appeals Process:

- Request for Reconsideration filed within 60 days of the notice of the revocation.
- CMS or its contractor, or the provider or supplier dissatisfied with a Reconsideration Determination may request an ALJ Hearing within 60 days from receipt of the Reconsideration Decision.
- CMS or its contractor, or the provider or supplier dissatisfied with the ALJ Hearing Decision may request Board review by DAB within 60 days from receipt of the ALJ's Decision.
- Provider or supplier dissatisfied with the DAB Decision may seek judicial review in District Court by filing a civil action within 60 days from receipt of the DAB's Decision.



- Bar to re-enrollment:
 - Bar is not discretionary.
 - Length of bar is discretionary for most revocations and is to be based on the severity of the basis for revocation.
 - Exceptions:
 - Failure to report final adverse action: 1-year if already enrolled, 3-years if new enrollee.
 - Failure to timely respond to revalidation request: 1-year bar.
 - Failed site visit: 2-year bar.
 - Submitting claims after license suspension or felony conviction or falsification of information: 3-year bar.



- Overpayment Action:
 - Physician (individual or group) and DMEPOS supplier for "final adverse action" from the date of the action.
 - Physician (individual or group) from the effective date of a change in practice location if change resulted in payment differential.
 - However, the overpayment can not be assessed prior to January 1, 2009, the effective date of the regulation.



Enrollment Applications Tips for Completing Forms

National Provider Identifier

NPI Numbers:

- Information publically available though NPPES website: caution regarding address listed as the Business Mailing Address.
- Retain confirmatory e-mail.
- Need to update when new license/s and/or provider numbers are issued.
- Protect NPI data:
 - Change password every six months.
 - Deactivate NPI if no longer in use.



What is PECOS?

- BBA of 1997 required collection of data regarding ownership and control for Medicare and Medicaidenrolled providers and suppliers.
- PECOS = Provider Enrollment, Chain, and Ownership System. It is the national electronic database for recording and retaining Medicare enrollment data.
- Fls began entering enrollment data for providers in July 2002 – only for new enrollees.
- Carriers began entering enrollment data for suppliers into PECOS in Nov. 2003 -- only for new enrollees.
- NSC maintained a separate enrollment database until September 2010.



What is PECOS?

- Currently, two mechanisms to get enrollment data entered into PECOS:
 - Submission of a complete set of Medicare enrollment forms --CMS 855 forms:
 - 855A (Institutional Providers)
 - 855B (Clinics/Group Practices and Certain Other Suppliers)
 - 855I (Physicians and Non-Physician Practitioners)
 - 855R (Reassignment of Medicare Benefits)
 - 855S (DMEPOS suppliers)
 - Use of Internet-based PECOS -- online alternative to the paper versions:
 - Must first obtain authorization to access and complete the applications.
 - Certification must be printed and sent via the mail.



- General Tips for the Completion of Medicare Enrollment Forms:
 - Names are important:
 - Legal entity: must match the IRS documentation and NPI data.
 - Trade name: implications for EFT.
 - Middle name or at least middle initial for each individual listed in forms.
 - If first name is an initial, may need to submit an official document.



- General Tips for the Completion of Medicare Enrollment Forms:
 - Full nine-digit zip codes.
 - Leave no blanks simply indicate "not applicable" or "pending" when appropriate.
 - If something is unusual, provide comments.
 - If in doubt, ask enrollment specialist how to complete.



- Completing the CMS 855 Forms:
 - Sections 3, 5 and 6: Final adverse action means:
 - A Medicare-imposed revocation of any Medicare billing privileges;
 - Suspension or revocation of a license to provide health care by any State licensing authority;
 - Revocation or suspension by an accreditation organization;
 - A conviction of certain Federal or State felony offenses within the last 10 years preceding enrollment, revalidation, or re-enrollment; or
 - An exclusion or debarment from participation in a Federal or State health care program.



- Completing the CMS 855 Forms:
 - Sections 3, 5 and 6: <u>Final adverse action</u> -- Federal or State Felony Offenses include:
 - Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
 - Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
 - Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.
 - Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.



- Completing the CMS 855 Forms:
 - Section 4: Practice Locations
 - Generally all providers and suppliers need to report all locations where services are rendered.
 - DMEPOS suppliers and IDTFs must separately enroll each practice location.
 - Legal versus trade name, be sure the signage is consistent with name listed.
 - Explain any unusual circumstances, e.g., hours of operation, unusual access to premises.



- Completing the CMS 855 Forms:
 - Section 5: Organizations with <u>Controlling Interest</u> or <u>5% or more</u> <u>Ownership Interest</u>:
 - Need to determine both direct and indirect ownership.
 - Include management company and possibly Section 8 Billing Agency.
 - Need to include entity with "financial ownership or control."



- Completing the CMS 855 Forms:
 - "Financial ownership or control":
 - Organization (Section 5) or individual (Section 6) who holds an interest in the mortgage, deed of trust, note, or other obligation secured by enrolling entity or any of the property or assets, and
 - Secured interest is 5% or more of the total property and assets.



- Completing the CMS 855 Forms:
 - Section 6: <u>Individuals</u> with <u>Controlling Interest</u> or <u>5% or more direct or indirect Ownership</u> interest:
 - All officers and governing body members (directors, trustees).
 - If LLC without officer or directors, persons with authority to enter into contracts and bind the entity.
 - Must include at least one managing employee: W-2 employee or contractor.



- Completing the CMS 855 Forms:
 - Partnership Interest: If the enrolling entity is a partnership then all partners [organizations (Section 5) or individuals (Section 6)] must be disclosed:
 - Irrespective of the percent of partnership interest.
 - Irrespective of whether general or limited partner.



- Completing the CMS 855 Forms:
 - Section 8 Billing Agency:
 - Company enrolling entity contacts with to prepare, edit, and/or submit claims.
 - If corporate parent serves as billing agent, the parent must also be listed in Section 8.



- Completing the CMS 855 Forms:
 - Key Persons:
 - Authorized Official/s: appointed official with legal authority to enroll in Medicare and commit entity to adhere to the laws and regulations.
 - <u>Delegated Official/s</u>: delegate by authorized official to report changes – must be an individual with ownership or controlling interest or a W-2 employee.

Note: Need to have a Section 6 form completed for anyone named as an authorized or delegated official.



- CMS 855I Form
 - Need to address issue of reassignment:
 - Will some or all of the individual's right to bill be reassigned to one or more groups?
 - Will the individual be retaining any billing rights?
 - Correspondence address: remember this is the individual's enrollment.
 - No need for EFT agreement if all rights to bill are being reassigned.
- CMS 855R Form
 - Is the reassignment from an employee or an independent contractor?



- Completing the CMS 855 Forms:
 - Contact for CMS 855 (Section 13):
 - List someone who is knowledgeable about this application and will be able to answer questions and respond quickly to requests for edits or supporting documentation.
 - Only for contact about the specific filing.
 - Contact for EFT:
 - List someone responsible for electronic deposits.
 - Does not have to be someone with signature authority on the account.



- Completing the CMS 855 Forms:
 - Why is the contact person important?
 - Enrollment rules allow application to be rejected for failing to respond to a request for additional/clarifying information or supporting documents.
 - Request triggers a 30-day clock.
 - Clock does not reset in situations when contractor contacts the enrollee to indicate not all of information was received.



- Completing the CMS 588 EFT Agreement:
 - Payment to bank account in exact name of enrolling entity, unless:
 - Letter from bank confirming account is held by the enrolling entity.
 - Payment is to a parent and letter from enrolling entity allowing payment to parent.
 - If provider has lending relationship with bank must enclose loan agreement/ statement that bank has waived its right of offset for Medicare receivables.



- Tips for Post-Submission Follow-up:
 - Call customer services in about a week if confirmatory e-mail regarding acceptance of filing is not received.
 - Most contractors have an online tracking process that provides updates on the status of the application.
 - If no online process, then call in few weeks to inquire about enrollment specialist assigned to process the enrollment forms.
 - Make an initial contact to the enrollment specialist – restate contact information.



- Tips for Post-Submission Follow-up:
 - Periodically check online status or followup with the assigned enrollment specialist:
 - To be sure that a development letter was not inadvertently sent to the wrong person or address.
 - To track the process to be sure forms are being timely processed.
 - Timely respond to all requests.
 - Keep copies of fax confirmations, overnight deliveries, telephone calls.



Ensuring Compliance

Incorporate Enrollment Procedures into Compliance Plan:

- Develop policies related to enrollment:
 - Forms completion, review, and submission.
 - Method for gathering data:
 - Obligation to provide complete information and notify of adverse final action (from practitioners, individuals and entities with ownership or controlling interest).
 - Licensure verifications.
 - Review of licensure laws.
 - Periodic review of reported enrollment data for accuracy.
- Identify key individuals responsible to oversee the process.

