Medicaid Provider Enrollment Compendium (MPEC)



The following represents official guidance issued by the Centers for Medicare and Medicaid Services' Center for Program Integrity and the Provider Enrollment and Oversight Group. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

Last Updated: 3/22/2021

Intended audience: State Medicaid Agencies (SMAs)

Message to providers: If you are a provider seeking to enroll to provide services to Medicaid or Children's Health Insurance Program (CHIP) beneficiaries, these programs are administered by individual states. You'll need to enroll in each state for which you would like to provide services to that state's eligible residents. To locate instructions for how to enroll in a specific state's Medicaid Program or CHIP, please conduct a web search using the terms "state"+ "Medicaid provider enrollment" (replace "state" with the name of the state where you seek to enroll). This will help you to locate information regarding a specific state's enrollment process.

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1.1 Introduction

A. Purpose for Medicaid Provider Enrollment Compendium

1. Sub Regulatory Guidance

This policy manual contains sub regulatory guidance and clarifications regarding how state Medicaid agencies are expected to comply with the following federal regulations at 42 CFR § 455:

- Subpart B "Disclosure of Information by Providers and Fiscal Agents," and
- Subpart E "Provider Screening and Enrollment"

The federal regulations at 42 CFR Part 455 include Subparts A through F; however, the information herein addresses only Part 455 Subparts B and E.

2. Applicability to Children's Health Insurance Program (CHIP)

All references to the Medicaid Program in this compendium are inclusive of CHIP.

Section 6401(b) of the Affordable Care Act amended section 1902 of the Act to require State Medicaid Programs to comply with the procedures established by the Secretary for screening providers and suppliers. Section 6401(c) of the Affordable Care Act amended section 2107(e) of the Act to make the provider and supplier screening requirements under section 1902 applicable to the Children's Health Insurance Program (CHIP).

Via a final rule published in the Federal Register on February 2, 2011, CMS established and implemented Medicaid provider screening requirements at 42 CFR Part 455, Subpart E. Per 42 CFR § 457.990, these regulations are applicable to CHIP and became effective on March 25, 2011.

3. Applicability to FFS Providers

Via a final rule published in the Federal Register on February 2, 2011, CMS established and implemented Medicaid provider screening requirements at 42 CFR Part 455, Subpart E. At that time, we did not finalize a proposed change to § 438.6 that would have required State managed care contracts to require network level providers enroll with the Medicaid agency as participating providers. This "exemption" was expressly limited to risk-based managed care. The "exemption" for risk-based managed care meant that the requirement at 455.410(b) for the state Medicaid agency to "require all ordering or referring physicians or other professionals providing services under the State plan or under a waiver of the plan to be enrolled as participating providers" applied to non-risk-based managed care providers such as physicians or

other professionals participating in primary case management programs under a waiver. Therefore, effective March 25, 2011, the regulations at Subpart E were applied to any provider under a fee for service model or a non-risk based managed care model.

In addition, Section 5005(b)(1) of the 21st Century Cures Act amended Section 1902(a) of the Act *by adding a new subparagraph (78) requiring that a State plan for medical assistance must* "provide that, not later than January 1, 2017, in the case of a State that pursuant to its State plan or waiver of the plan for medical assistance pays for medical assistance on a fee-for-service basis, the State shall require each provider furnishing items or services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable)."

4. Applicability to Network Providers

Via a final rule published in the Federal Register on February 2, 2011, CMS established and implemented Medicaid provider screening requirements at 42 CFR Part 455, Subpart E (see 1.1.A.3. "Applicability to FFS Providers" above). Via a final rule published in the Federal Register on May 6, 2016, CMS finalized the federal regulation at 42 CFR 438.602(b) to apply these requirements to the remainder of providers furnishing, ordering, or referring items or services under the State Medicaid plan. As discussed in the May 6, 2016 rule "the requirements at 42 CFR part 455, subparts B and E are applicable to all provider types eligible to enroll as participating providers in the state's Medicaid program as it is integral to the integrity of the Medicaid program that all providers that order, refer or furnish services to Medicaid beneficiaries are appropriately screened and enrolled." (81 FR 27602)

In addition, Section 5005(b)(2) of the 21st Century Cures Act amended Section 1932(d) of the Act *by adding a new subparagraph (6)* to provide that, "not later than January 1, 2018, a State shall require that, in order to participate as a provider in the network of a managed care entity that provides services to, or orders, prescribes, or certifies eligibility for services for, individuals who are eligible for medical assistance under the State plan under this title (or under a waiver of the plan) and who are enrolled with the entity, the provider is enrolled consistent with section 1902(kk) with the State agency administering the State plan under this title. Such enrollment shall include providing to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier, Federal taxpayer identification number, and the State license or certification number of the provider."

Although the final rule published in the federal register on May 6, 2016 established the federal regulation at 42 CFR 438.602(b) requiring the enrollment of network providers in the state's

Medicaid program, and the original deadline for this requirement was with contract rating periods beginning on or after July 1, 2018, Section 5005(b)(2) of the 21st Century Cures Act supersedes the May 6, 2016 rulemaking with respect to this deadline. In summary, effective January 1, 2018, providers under all service delivery models may furnish services to Medicaid beneficiaries, including as ORPs, only where the state has executed a provider agreement with the provider and performed all applicable screening, unless an exception applies as described herein.

B. Description of Content

This manual includes selected definitions, a description of the statutory basis and background for the requirements at Subparts B and E, and guidance for states specific to topics related to compliance with the regulations at Subparts B and E.

1. Superseded Guidance

This manual includes, abolishes, or supersedes guidance that was previously published in the CMCS Informational Bulletin dated December 23, 2011 "Subject: Medicaid/CHIP Provider Screening and Enrollment"

C. Procedures for Updates to this Compendium

This document will be updated and expanded. Please refer to the "Last Updated" information to see the date this document was most recently updated. When the document is updated, changes and edits will appear in red font for one update cycle.

1.1.1 Background

State Medicaid Plans pay providers for furnishing covered services to eligible beneficiaries, including either on a fee-for-service basis or through risk-based managed care arrangements. If state Medicaid agencies pay fraudulent providers, either directly or through managed care plans, for services that the providers did not furnish or for services they did furnish to beneficiaries they knew had no need for the services: (1) Medicaid funds are diverted from their intended purpose, (2) beneficiaries who need services may not receive them, and (3) beneficiaries who do not need services may be harmed by unnecessary care. Identifying overpayments due to fraud--- and recovering those overpayments from providers that engaged in the fraud---is resource-intensive and can take years. In contrast, keeping ineligible entities and individuals from enrolling in State Medicaid Plans as providers in the first place allows the program to avoid paying claims to such parties and then attempting to identify and recover those overpayments. Provider screening enables states to identify such parties before they are able to enroll and start billing.

1.1.2 Selected Definitions

A. Regulatory Definitions under §§ 455.2, 455.101, and 400.203

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Conviction or **Convicted** means that a judgment of conviction has been entered by a federal, state, or local court, regardless of whether an appeal from that judgment is pending.

Disclosing entity means a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent.

Fiscal agent means a contractor that processes or pays vendor claims on behalf of the SMA.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means an ownership interest in an entity that has an ownership interest in the disclosing entity. This term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managed care entity (MCE) means managed care organizations (MCOs), pre-paid inpatient health plans (PIHPs), pre-paid ambulatory health plans (PAHPs), primary case care management (PCCMs), and health improvement organizations (HIOs).

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 operation of an institution, organization, or agency.

Other disclosing entity means any other Medicaid disclosing entity and any entity that does not participate in Medicaid, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XVIII, or XX of the Act. This includes:

- (a) Any hospital, skilled nursing facility, home health agency, independent clinical laboratory, renal disease facility, rural health clinic, or health maintenance organization (meaning all MCOs) that participates in Medicare (title XVIII);
- (b) Any Medicare intermediary or carrier; and

(c) Any entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which it claims payment under any plan or program established under title V or title XX of the Act.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

- (a) Has an ownership interest totaling 5 percent or more in a disclosing entity;
- (b) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;
- (c) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;
- (d) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;
- (e) Is an officer or director of a disclosing entity that is organized as a corporation; or
- (f) Is a partner in a disclosing entity that is organized as a partnership.

Practitioner means a physician or other individual licensed under state law to practice his or her profession.

Provider means either of the following:

- (1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.
- (2) For the managed care program, any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the state in which it delivers the services.

Significant business transaction means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of \$25,000 and 5 percent of a provider's total operating expenses.

Subcontractor means—

- (a) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or
- (b) An individual, agency, or organization with which a fiscal agent has entered into a contract, agreement, purchase order, or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicaid agreement.

Supplier means an individual, agency, or organization from which a provider purchases goods and services used in carrying out its responsibilities under Medicaid (e.g., a commercial laundry, a manufacturer of hospital beds, or a pharmaceutical firm).

Termination means—

- (1) For a—
- (i) Medicaid provider, a State Medicaid Program has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired; and
- (ii) Medicare provider, supplier or eligible professional, the Medicare Program has revoked the provider or supplier's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired.
- (2)(i) In all three programs, there is no expectation on the part of the provider or supplier or the state or Medicare Program that the revocation is temporary.
- (ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated.
- (3) The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked "for cause" which may include, but is not limited to—(i) fraud; (ii) integrity; or (iii) quality.

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

B. Selected Definitions under § 438.2

Network provider: Any provider, group of providers, or entity that has a network provider agreement with a MCO, PIHP, or PAHP, or a subcontractor, and receives Medicaid funding

directly or indirectly to order, refer or render covered services as a result of the state's contract with an MCO, PIHP, or PAHP. A network provider is not a subcontractor by virtue of the network provider agreement.

Subcontractor: An individual or entity that has a contract with an MCO, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCO's, PIHP's, PAHP's, or PCCM entity's obligations under its contract with the State. A network provider is not a subcontractor by virtue of the network provider agreement with the MCO, PIHP, or PAHP.

C. Other Definitions and Terms

1. Definitions Relevant When the SMA Relies Upon Screening Conducted by Medicare

Accreditation is a process of review that healthcare organizations participate in to demonstrate the ability to meet predetermined criteria and standards established by a professional accrediting organization. CMS has established provider accreditation requirements for home health agencies, hospices, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) agencies that participate in the Medicare program. For certain programs and services, Medicare requires organizations to become accredited by an approved accrediting organization before they are able to participate or enroll with Medicare. While accreditation is a prerequisite of participation with Medicare for certain provider types, it does not guarantee approval of enrollment with Medicare. As such, SMAs should not accept accreditation in place of an approved enrollment with Medicare.

Certification is the process by which a State Agency (SA), contracted with CMS, performs a survey of a provider or supplier to determine whether the provider is compliant with standards required by Federal regulations. The SA does not have the authority or function to make a Medicare participation determination on its own. The authority for determining if a provider may participate with Medicare is instead delegated to the appropriate CMS Regional Office (RO). The RO relies upon the SA certification as crucial evidence in determining the provider's eligibility to participate with Medicare. Once the RO receives the certification from the SA, the RO determines if a provider is eligible to participate in the Medicare program. The RO submits the determination on to the appropriate Medicare Administrative Contractor (MAC) for inclusion with the enrollment application, as it is a requirement of enrollment for specific provider types. The MAC then enters this information into PECOS and notifies the provider of the decision. It is important to note that a successful certification does not guarantee that the RO will approve the provider for enrollment with Medicare, as there are other factors involved. As such, SMAs should not accept certification in place of an approved enrollment with Medicare.

CMS approved accreditation organization means a recognized independent accreditation organization approved by CMS under §424.58.

2. Other General Definitions

Exclusion from participation in a federal health care program (e.g., Medicare and Medicaid) is a penalty imposed on a provider by the Office of Inspector General (OIG) under § 1128 or 1128A of the Social Security Act. Individuals and entities may be excluded by the OIG for misconduct ranging from fraud convictions, to patient abuse, to defaulting on health education loans. States may also exclude providers from their Medicaid Programs under state law or pursuant to 42 CFR § 1002.2.

The **National Provider Identifier (NPI)** is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard. The NPI is a unique identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use NPIs in administrative and financial transactions adopted under HIPAA. The NPI must be used in lieu of legacy provider identifiers in the HIPAA standards transactions. As outlined in the Federal Regulation at 45 CFR Part 162 Subpart D, The Health Insurance Portability and Accountability Act of 1996 (HIPAA), covered providers must also share their NPI with other providers, health plans, clearinghouses, and any entity that may need it for billing purposes. Some entities do not qualify to receive NPIs. Specifically, any entity that does not meet the definition of a health care provider as defined in 45 CFR § 160.103 may not apply for an NPI. Such entities include billing services, value-added networks, repricers, health plans, health care clearinghouses, non-emergency transportation services, and others who do not furnish health care.

A **Medicaid overpayment** means the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act. After Medicaid identifies an overpayment, the overpayment amount becomes a debt the provider owes the State Medicaid Agency.

Private Practice in regard to physical therapy means any practice setting where the therapist maintains office space and furnishes services only in that space or the patient's home. Private practice settings do not include institutional settings which are listed at 1.8.1.D.1.a.

Rating period means a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS.

1.2 Basic Statutory and Regulatory Framework

1.2.1 42 CFR Subpart B

A. Statutory and Regulatory Background for 42 CFR 455 Subpart B

Section 1902(a)(27) of the Act provides general authority for the Secretary to require provider agreements under the State Medicaid Plans with every person or institution providing furnishing services under the State plan. Under these agreements, the Secretary may require information regarding any payments claimed by such person or institution for furnishing providing services under the State plan.

Section 2107(e) of the Act provides that certain title XIX and title XI provisions apply to States under title XXI, including 1902(a)(4)(C) of the Act, relating to conflict of interest standards, and 1902(a)(77) and (kk), relating to screening, oversight and reporting requirements.

Via the February 2, 2011 final rule "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, Final Rule" (Federal Register Volume 76, pages 5862 - 5971):

- The federal regulation at 455.104 was finalized adding to the disclosure requirements collection of SSNs and DOBs of persons with an ownership or control interest in the disclosing entity.
- The federal regulation at § 455.104(b)(1)(i) was modified to clarify from whom the name and address must be provided and to require the disclosing entity to supply primary business address as well as every business location and P.O. Box address, if applicable.
- The federal regulation at § 455.104(b)(2) was clarified regarding to whom the spouse, parent, child, or sibling is related.
- The federal regulation at § 455.104(b)(4) was amended to require managing employees to provide SSNs and DOBs.

Via the May 6, 2016 final rule "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Final Rule" (Federal Register Volume 81, pages 27498 -27901):

 The federal regulation at 438.602(b)(1) was finalized to require the State to screen and enroll, and periodically revalidate, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of 42 CFR part 455, subparts B and E. This requirement extends to PCCMs and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries.

1. Assuring confidentiality of Personally Identifiable Information (PII)

The "Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as required by the Balanced Budget Act" was signed by the Secretary and sent to the Congress on January 26, 1999. This report outlines the provisions of a mandatory collection of SSNs and EINs effective on or after April 26, 1999.

B. Compliance with Part 455, Subpart B – State Plan Requirements

Section 455.103 requires that a State's Medicaid Plan must provide that the requirements of §§ 455.104 through 455.106 are met.

Under § 430.35(b), if a state fails to change its approved plan to conform to a new federal requirement, the state is subject to withholding of federal matching payments, in whole or in part, until the state's plan is in compliance with federal requirements.

C. Education on Requirements

CMS recommends that states educate providers regarding the disclosure requirements in Part 455. The means of education are within the state's discretion; examples may include provider enrollment websites, provider information bulletins, and inclusion in provider agreements.

1.2.2 42 CFR 455 Subpart E

A. Statutory and Regulatory Background for 42 CFR 455 Subpart E

Section 6401(a) of the Affordable Care Act (as amended by section 10603 of the Affordable Care Act) amended section 1866(j) of the Social Security Act (the Act) by adding a new paragraph: "(2) Provider Screening", which sets forth the following:

• Section 1866(j)(2)(A) of the Act requires the Secretary, in consultation with the Department of Health and Human Services' Office of the Inspector General (OIG), to establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under Medicare and Medicaid.

- Section 1866(j)(2)(B) of the Act requires the Secretary to determine the level of screening to be conducted according to the risk of fraud, waste, and abuse with respect to the category of provider or supplier.
- Section 1866(j)(2)(C) of the Act requires the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier, to be used by the Secretary for program integrity efforts.

Section 6401(b) of the Affordable Care Act amended section 1902 of the Act to require State Medicaid Plans to comply with the procedures established by the Secretary for screening providers and suppliers. Section 6401(c) of the Affordable Care Act amended section 2107(e) of the Act to make the provider and supplier screening requirements under section 1902 applicable to the Children's Health Insurance Program (CHIP).

Via a final rule published in the Federal Register on February 2, 2011, CMS established and implemented Medicaid provider screening requirements at 42 CFR Part 455, Subpart E. Per 42 CFR § 457.990, these regulations are applicable to CHIP. These provisions became effective on March 25, 2011.

Section 1902(a)(77) of the Act requires that State Medicaid Plans comply with the provider and supplier screening, oversight, and reporting requirements in section 1902(kk). Section 1902(kk) contains requirements related to screening, provisional periods of enhanced oversight for new providers and suppliers, disclosure, temporary moratoria on enrollment of new providers and suppliers, compliance programs, reporting of adverse provider actions, and enrollment and NPI of ordering or referring providers. Sections 1902(a)(77) and 1902(kk) were added to the Act by section 6401(b) of the Affordable Care Act.

Section 1902(a)(39) of the Act requires that State Medicaid Programs terminate the participation of any individual or entity if that individual or entity is terminated under Medicare or by any other Medicaid Program. Section 1902(a)(39) was amended by section 6501 of the Affordable Care Act. The federal regulations at Part 455, Subpart E implement the provider screening and enrollment requirements of sections 1902(a)(77) and 1902(a)(39) of the Act.

B. Compliance with Part 455, Subpart E – State Plan Requirements

Section 455.405 requires that a State's Medicaid Plan must provide that the requirements of §§ 455.410 through 455.450 and § 455.470 are met. To facilitate compliance with these State Plan requirements, a Medicaid State Plan preprint is available as Attachment A to this document.

Under § 430.35(b), if a state fails to change its approved plan to conform to a new federal requirement, the state is subject to withholding of federal matching payments, in whole or in part, until the state's plan is in compliance with federal requirements.

C. Education on Requirements

CMS recommends that states educate providers regarding the enrollment and screening requirements in Part 455. The means of education are within the state's discretion; examples may include provider enrollment websites, provider information bulletins, and inclusion in provider agreements.

1.3 Medicaid Providers: Categories and Definitions

A. Medicaid "Providers"

For Medicaid, we use the terms "providers" or "Medicaid providers" when referring to all Medicaid health care providers, including individual practitioners, institutional providers, and providers of medical equipment or goods related to care.

B. Ordering or Referring Physicians or Other Professionals (ORP)

Federal regulations at §§455.410(b) and 455.440 implement the statutory provisions relating to ordering or referring physicians or other professionals at § 1902(kk)(7)(A) and (B) of the Act. Under 455.410(b), the SMA must require all ordering or referring physicians or other professionals providing furnishing services under the State plan or under a waiver of the plan to be enrolled as participating providers. Under § 455.440, the SMA must require all claims for payment for items and services that were ordered or referred to contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred such items or services.

Based on §1902(a)(78), we interpret the statutory terms "ordering" and "referring" to include prescribing (either drugs or other covered items) or sending a beneficiary's specimens to a laboratory for testing or referring a beneficiary to another provider or facility for covered services. The definition also includes certifying a beneficiary's need for a service.

Examples of "ordering or referring" include:

- Prescribing (either drugs or other covered items) for a beneficiary
- Sending a beneficiary's specimens to a laboratory for testing
- Ordering imaging services for a beneficiary
- Ordering durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) for a beneficiary

- Referring a beneficiary to another provider or facility for covered services (referrals only count to the extent that a referral is required for coverage of a referred service)
- Determining or certifying a beneficiary's need for a covered item or service (e.g., outpatient drug counseling or home health services or nursing facility services) where the determination or certification by a physician or other professional that a beneficiary needs or qualifies for receipt of an item or service is required for payment of the claim

With respect to the disclosure and screening requirements at Subparts B and E, ORP providers are not exempt.

When enrolling ORPs, a State Medicaid Plan has the discretion to enroll ORPs as a separate enrollment category for purposes such as, but not limited to, payment-eligibility, tracking, or reporting. For example, the SMA may opt to exclude ORPs from lists of providers represented as available to provide services to Medicaid beneficiaries.

Under this approach a SMA may, at its discretion, allow providers to enter into private pay agreements with beneficiaries in circumstances where a provider has enrolled only for the purposes of ordering, referring, or prescribing and cannot request reimbursement for other services.

Further, the SMA may use an abbreviated form to enroll ORPs; the SMA should take into consideration the requirement that ORPs must be fully screened at the appropriate risk level upon new enrollment and revalidation.

In some circumstances, if an ordering or referring provider is not enrolled, it may be appropriate for the SMA to pend the claim from the provider performing the services which were ordered or referred to allow for the ORP to become enrolled and after such enrollment pay the claim.

A SMA may also, at its discretion, provide access to enrollment information to providers so that providers can determine that ordering and referring providers are enrolled in the Medicaid program.

C. Concept of "Institutional" Provider

Medicaid covers certain inpatient, comprehensive services as institutional benefits. The term "institutional" has several meanings in common use, but a particular meaning for Medicaid. In Medicaid coverage, "institutional services" refers to specific benefits authorized in the Social Security Act. These are hospital services, and certain long-term care services. In some cases there are Medicaid-only provider types that may be considered institutional. The SMA may find it helpful to use the criteria below to determine whether a provider is institutional. These

criteria are not fully determinative, as there are other provider types considered to be institutional and to which the application fee applies. See Section 1.8.1.C.1 for more information regarding these provider types. Once a state has determined that a provider/supplier is institutional, they should apply that determination to all providers/suppliers of the same type.

Institutional benefits share the following characteristics:

- Institutions are residential facilities, and assume total care of the individuals who are admitted.
- The comprehensive care includes room and board. Other Medicaid services are specifically prohibited from including room and board.
- The comprehensive service is billed and reimbursed as a single bundled payment. (Note that states vary in what is included in the institutional rate, versus what is billed as a separately covered service; for example, physical therapy may be reimbursed as part of the bundle or as a separate service)
- Institutions must be licensed and certified by the state, according to federal standards.
- Institutions are subject to survey at regular intervals to maintain their certification and license to operate.
- There may be different Medicaid eligibility rules for residents of an institution; therefore, access to Medicaid services for some individuals may be tied to need for institutional level of care.

Once a SMA has determined that a provider/supplier is institutional, it should apply that determination to all providers/suppliers of the same type.

See section 1.8.1.C.1.a "Institutional Providers" for information concerning "institutional providers" for purposes of application fee payment.

D. Risk Levels for Provider Types Also Existing in Medicare

1. Regulations Used to Determine Medicaid Risk Categories

Consistent with section 1902(kk)(1) of the Act, for provider types that exist in both Medicare and Medicaid, the SMA must assign providers to the same or higher risk category applicable under Medicare under 42 CFR § 424.518.

a. Medicare Screening Levels that Apply to Medicaid

Specifically, the SMA should rely on the following regulatory citations indicating the list of providers assigned to each Medicare risk categories:

- §424.518(a)(1) indicates providers the SMA must assign at a minimum to the "limited" risk category
- §424.518(b)(1) indicates providers the SMA must assign at a minimum to the "moderate" risk category
- §424.518(c)(1) indicates providers the SMA must assign at a minimum to the "high" risk category (please note that, specific to the "high" risk category, the next section describes that there is additional Medicaid-specific criteria a SMA must follow at 455.450(e))

A SMA may not assign a Medicaid provider to a risk category lower than that which Medicare has assigned to that same provider type.

If a provider potentially fits within more than one risk level, the highest screening level is applicable.

2. Providers Designated "Limited" Risk

"Limited" -- Section 424.518(a)(1) lists the following provider types under the "limited" risk category:

- Physician or non-physician practitioners (including nurse practitioners, certified registered nurse anesthetists, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics
- Ambulatory surgical centers (ASCs)
- Competitive Acquisition Program/Part B Vendors
- End-stage renal disease facilities (ESRDs)
- Federally qualified health centers (FQHCs)
- Histocompatibility laboratories
- Home infusion therapy suppliers

- Hospitals, including critical access hospitals (CAHs), Department of Veterans Affairs hospitals, and other federally-owned hospital facilities
- Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act
- Mammography screening centers
- Mass immunization roster billers
- Opioid treatment programs (if § 424.67(b)(3)(ii) applies)
- Organ procurement organizations (OPOs)
- Pharmacies newly enrolling or revalidating via the CMS-855B application
- Radiation therapy centers (RTCs)
- Religious non-medical health care institutions (RNHCIs)
- Rural health clinics (RHCs)
- Skilled nursing facilities (SNFs)
- 3. Providers Designated "Moderate" Risk

"Moderate" -- Section 424.518(b)(1) lists the following provider types under the "moderate" risk category:

- Ambulance service suppliers
- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Hospice organizations
- Independent clinical laboratories (ICLs)

- Independent diagnostic testing facilities (IDTFs)
- Physical therapists enrolling as individuals or as group practices
- Portable x-ray suppliers (PXRSs)
- Prospective (newly enrolling) opioid treatment programs (OTP) that have been fully and continuously certified by SAHMSA since October 23, 2018
- Revalidating DMEPOS suppliers
- Revalidating home health agencies (HHAs)
- Revalidating Medicare diabetes prevention program (MDPP) suppliers
- Revalidating opioid treatment programs

4. Providers Designated "High" Risk

"High" risk can apply to individual or organizational providers. Two federal regulations, §§ 424.518(c) and 455.450(e), are used to indicate the providers and provider types the SMA must categorize as "high" risk. Section 424.518(c)(1) lists the following provider types under the "high" risk category:

- Prospective (newly enrolling) DMEPOS suppliers
- Prospective (newly enrolling) home health agencies (HHAs)
- Prospective (newly enrolling) Medicare diabetes prevention program MDPP suppliers
- Prospective (newly enrolling) opioid treatment programs that have not been fully and continuously certified by SAHMSA since October 23, 2018

Section 455.450(e) lists the provider types that must additionally be elevated to the "high" risk category. As provided in the regulation and prior clarifying guidance, the SMA must adjust the categorical risk level of a particular provider from "limited" or "moderate" to "high" when any of the following four situations occur:

- The SMA imposes a payment suspension on a provider based on a credible allegation of fraud, waste or abuse. The provider's risk remains "high" for 10 years beyond the date of the payment suspension.
- A provider that, upon applying for enrollment or revalidation, is found to have an existing State Medicaid Plan overpayment. The risk remains "high" while the provider continues to have an existing overpayment. In this scenario, when there are multiple enrollments under a single TIN, the SMA is required to adjust the risk level of the enrollment with the overpayment but may also opt to adjust the risk level for all enrollments connected to a TIN with an existing overpayment. An overpayment that meets the criteria to bump a provider to "high" risk is \$1500* or greater and all of the following:
 - o Is more than 30 days old
 - Has not been repaid at the time the application was filed
 - o Is not currently being appealed
 - Is not part of a SMA-approved extended repayment schedule for the entire outstanding overpayment

*Note: The \$1500 threshold is an aggregate of all outstanding debts and interest, to include the principal overpayment balance amount and the accrued interest amount for a given provider.

- Within the previous 10 years, the provider has been excluded (and since reinstated)
 by the OIG or another state's Medicaid Program. The provider's risk remains "high"
 for 10 years beyond the effective date of the exclusion.
- The SMA or CMS in the previous 6 months lifted a temporary moratorium for the particular provider type and a provider that was prevented from enrolling based on the moratorium applies for enrollment as a provider at any time within 6 months from the date the moratorium was lifted.

E. Risk Levels for Medicaid-Only Providers

Certain provider types are recognized by State Medicaid Plans but not Medicare; this means that they are not listed in § 424.518. The SMA is required to assign Medicaid-only categories of providers to an appropriate risk level. For example, SMAs that enroll non-emergency transportation providers such as Uber and Lyft under their state plan, have discretion as to which risk level they assign to this provider type because non-emergency transportation providers are Medicaid-only providers.

In general, in order to assign appropriate risk levels – the SMA should examine its Medicaid Program to determine which of these provider types present an increased risk of fraud, waste or abuse to its Medicaid Program. The SMA is uniquely qualified to understand issues involved with balancing beneficiaries' access to medical assistance and ensuring the fiscal integrity of the State Medicaid Program; thus, the SMA has the discretion to make its own risk level determinations concerning these provider types.

- For the Medicare Program, CMS was required under Section 1866(j)(2)(B) of the Act to determine the level of screening applicable to providers and suppliers according to the risk of fraud, waste, and abuse that CMS determined is posed by particular provider and supplier categories. CMS documented what was considered in making these determinations in the discussion beginning on page 5867 of the February 2, 2011 final rule. To review this discussion in the Federal Register, refer to Section II.A.3. "General Screening of Providers" (76 FR 5867).
- When assigning Medicaid-only providers to risk categories, we recommend the SMA
 assess risk using similar considerations as CMS used to assess risk in Medicare,
 potentially including, and not limited to audit reports, such as, but not limited to:
 - o GAO or OIG final reports
 - Insight of law enforcement partners
 - Congressional testimony
 - Level of administrative enforcement actions for a particular provider type
 - Assessment of the level of state and federal oversight for a particular provider type
 - Assessment of the level of oversight by accrediting bodies
 - Aggregate experience with a particular provider type

1.4 Disclosures

1.4.1 Ownership and Control Interests (§§ 455.102 through 455.104)

A. General Requirements

Federal regulatory provisions regarding disclosure of ownership and control interests are at Part 455, Subpart B (§§ 455.100 through 455.106).

1. State Medicaid Agency Responsibilities

Under § 455.103, a state plan must provide that the requirements of §§ 455.104 through 455.106 are met.

a. Delegating Collection of Disclosures to a Network Plan

Under the requirement at 438.602, SMAs may delegate screening activities required under Part 455 Subpart E to a network plan. However, based upon privacy and security concerns including data breaches that include personally identifiable information (PII), we are not allowing SMAs to delegate the collection of disclosures under Subpart B in a manner that results in a single provider entity disclosing the information to more than one entity. A provider that is providing furnishing services on behalf of the state Medicaid plan should not be required to disclose PII to multiple entities with which the SMA contracts. In an effort to mitigate the risk that PII will be compromised in a data breach, we further believe the SMA should store PII in the fewest number of locations necessary to meet the requirement of the regulations at Subparts B and E. Also refer to Section 1.5.3.B.1 "SMA Bears Responsibility for Screening Activities Delegated to its Contractors."

B. Parties Subject to Disclosure Requirements (§ 455.104(a))

Under § 455.104(a), the SMA must obtain disclosures from (1) disclosing entities, (2) fiscal agents, and (3) managed care entities (definitions of these three terms are in section 1.1.2 "Selected Definitions").

Information on how the disclosure requirements at 455 Subpart B apply to individuals (e.g., owners, individuals in specific roles, etc.) within these parties is described under section "C. Information to be Disclosed."

C. Information to be Disclosed (§ 455.104(b))

1. Regulatory Requirements

Under § 455.104(b), the SMA must require that disclosing entities, fiscal agents, and managed care entities disclose the following:

- a. Identifying Information Regarding Persons with Ownership or Control Interests (§ 455.104(b)(1)):
 - The name and address of any person (individual or corporation) with an ownership
 or control interest in the disclosing entity, fiscal agent, or managed care entity. The
 address for corporate entities must include, as applicable, primary business address,
 every business location, and P.O. Box address.
 - Date of birth and Social Security Number (SSN) of any individual with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity.

 Other tax identification number (TIN) (in the case of a corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest.

b. Ownership or Control Relationships (§ 455.104(b)(2)):

- Whether the person (individual or corporation) with an ownership or control
 interest in the disclosing entity (or fiscal agent or managed care entity) is related to
 another person with ownership or control interest in the disclosing entity as a
 spouse, parent, child, or sibling;
- Whether the person (individual or corporation) with an ownership or control
 interest in any subcontractor in which the disclosing entity (or fiscal agent or
 managed care entity) has a 5 percent or more interest is related to another person
 with ownership or control interest in the disclosing entity as a spouse, parent, child,
 or sibling.

c. Name of Any Other Disclosing Entity

• The name of any other disclosing entity (or fiscal agent or managed care entity) in which an owner of the disclosing entity (or fiscal agent or managed care entity) has an ownership or control interest (§ 455.104(b)(3)).

d. Managing Employee Disclosure

• The name, address, date of birth, and SSN of any managing employee of the disclosing entity (or fiscal agent or managed care entity) (§ 455.104(b)(4)).

Note that practitioners and groups of practitioners are not included within the definition of disclosing entities under 455.101 and thus are not required to provide disclosures pursuant to § 455.104.

There are not exceptions to the managing employee disclosure requirement. To the extent any individual meets the definition of "managing employee" under § 455.101, their information is required to be disclosed.

- 2. Identifying Information: Individuals/Entities without TINs
- a. Process for Individuals/Entities without TINs

Consistent with Part 455 Subpart B, the TINs (employer identification numbers or social security numbers) of all entities and individuals with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity and all managing employees must be disclosed. If the SMA or its contractor receives an initial, reactivation, revalidation, or change of ownership application from a provider and the provider fails to disclose the TIN of a particular organization or individual, the SMA or its contractor shall follow normal development procedures for requesting the TIN. In doing so, if the SMA or its contractor learns or determines that the TIN was not furnished because the entity or individual in question does not have a TIN, CMS suggests (but does not require) that the SMA or its contractor use the following process:

- The SMA should ask the provider (via any means) whether the person or entity is able to obtain a TIN or, in the case of individuals, an individual taxpayer identification number (ITIN). Only one inquiry is needed.
- If the provider fails to respond to the SMA's inquiry within a state-determined timeframe, the SMA may deny the application.
- If the provider states that the person or entity is able to obtain a TIN or ITIN, the SMA should send an e-mail, fax, or letter to the provider stating that (i) the person or entity must obtain a TIN/ITIN and (ii) the provider must furnish the TIN/ITIN to the SMA.
- If the provider states that the person or entity is unable to obtain a TIN or ITIN, the SMA should send an e-mail, fax, or letter to the provider stating that (i) the provider must submit written documentation (in a form and manner to be determined by the SMA) to the SMA explaining why the person or entity cannot legally obtain a TIN or ITIN.
- If the provider submits the explanation described above, the SMA should determine
 whether the explanation is satisfactory. The state may choose to vet the entity or
 individual via other sources. If the explanation is not satisfactory, the SMA may deny
 the application as described below under b. "Denial of Enrollment for
 Individuals/Entities without TINs."

b. Denial of Enrollment for Individuals/Entities without TINs

If the provider fails to timely respond to the contractor's inquiry in (a) or fails to timely furnish the TIN/ITIN, the SMA or its contractor shall reject the application in accordance with the procedures identified in this chapter, unless the SMA determines that termination or denial of enrollment is not in the best interests of the State Medicaid Plan and the SMA documents that determination in writing.

- 3. Ownership Disclosure: Determination of Ownership or Control Percentages
- a. Difference between Direct and Indirect Ownership

A direct owner has an actual ownership interest in the disclosing entity (e.g., owns stock in the business, etc.), whereas an indirect owner has an ownership interest in an entity that, in turn, has an ownership interest in the disclosing entity. Many organizations that directly own a disclosing entity are themselves wholly or partly owned by other organizations (or even individuals). This may be the result of the use of holding companies and parent/subsidiary relationships.

When disclosures are required, an enrollment record must capture both direct and indirect owners. Indirect owners should not be listed under a separate enrollment. If a SMA uses a system to capture ownership interest information, the system should accommodate multiple layers of ownership within a single record of enrollment. The combination of indirect and direct ownership may be greater than 100 percent.

Consider the following example:

The provider listed on the Medicaid enrollment application is an ambulance company that is wholly (100 percent) owned by Company A. Company A is considered to be a direct owner of the provider (the ambulance company), in that it actually owns the assets of the business. Now assume that Company B owns 100 percent of Company A. Company B is considered an indirect owner - but an owner, nevertheless - of the provider. In other words, a direct owner has an actual ownership interest in the provider, whereas an indirect owner has an ownership interest in an organization that owns the provider.

b. Determining Percentages of Ownership Interest (§ 455.102)

Under § 455.104(b), the SMA must require that disclosing entities, fiscal agents, and managed care entities disclose information including the name and address of any person (individual or corporation) with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity. "Person with an ownership or control interest" is defined at § 455.101 to include individuals or corporations that have a direct, indirect, or a combination of direct and indirect ownership interest totaling 5 percent or more in a disclosing entity. This interest

includes any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity.

The federal regulation at § 455.102 describes how the SMA must determine percentages of ownership interest, as follows:

i. Indirect Ownership Interest (§ 455.102(a))

The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation which owns 80 percent of the stock of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation which owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

ii. Person with an Ownership or Control Interest (§ 455.102(b))

Ownership interest also includes interests in mortgages, deeds of trust, notes, and other obligations. An organization or individual that has a 5 percent or greater whole or part interest in any mortgage, deed of trust, note, security interest, or other obligation secured (in whole or in part) by the provider or any of the property or assets of the provider must be disclosed under § 455.104(b). This frequently will include banks, other financial institutions, and investment firms.

In order to determine percentage of ownership, mortgage, deed of trust, note, or other obligation, the percentage of interest owned in the obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. If B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and needs not be reported.

c. Publicly Traded Entities

There is not an exception for publicly traded entities.

d. Non-Profit Entities

Non-profit entities generally do not have owners unless state law permits such ownership. However, if a non-profit entity has managing employees, to the extent these individuals meet the definition of "managing employee" under § 455.101; they would have to be disclosed as

such. In addition, as discussed further below, entities, including non-profit entities, that are organized as corporations must provide disclosures regarding their officers and directors.

e. Government-Owned Entities

There is not an exception for government-owned entities. Government-owned entities likewise need to disclose anyone meeting the definition of "managing employee," and would only need to disclose board members if the entity was organized as a corporation or if that individual meets the definition of "managing employee." See 1.4.C.1.d "Managing Employee Disclosure."

f. American Indian and Alaska Native (AI/AN) Entities

There is not an exception for organizations owned by Al/AN individuals or health care facilities owned and operated by Al/AN tribes and tribal organizations. In addition, Federal health programs operated by the Indian Health Service, Tribes and Tribal organizations under the Indian Health Care Improvement Act and the Indian Self-Determination and Education Assistance Act, and urban Indian organizations under the Indian Health Care Improvement Act are subject to the disclosure and screening requirements under 455 Subparts B and E. Al/AN and tribal entities, and Indian Health Programs would need to disclose anyone meeting the definition of "managing employee," and would only need to disclose Board members if the entity was organized as a corporation. See 1.4.C.1.d "Managing Employee Disclosure."

g. Disregarded Entities

In general, a "disregarded entity" is a term the IRS uses for a limited liability company (LLC) that — for federal tax purposes only — is effectively indistinguishable from its single owner/member. The LLC's income and expenses are shown on the owner's personal tax return. The LLC itself does not pay taxes.

If an enrolling provider claims that it is a disregarded entity, CMS suggests (but does not require) that the SMA or its enrollment contractor confirm the provider's legal business name (LBN) and tax identification number (TIN) by accepting any government form (such as a W-9) from the enrolling provider that lists its LBN and TIN.

Typically, line 1 of the W-9 indicates the LBN of the facility and line 2 indicates the operating name of the facility; however, if the entity is considered by the IRS to be a disregarded entity, these forms are prepared differently. The SMA or its enrollment contractor are encouraged to review the W-9 instructions for disregarded entities when processing these applications.

4. Additional Guidance Regarding Individuals with Control Interests

Under § 455.101, a person with an ownership or control interest includes (1) an officer or director of a disclosing entity that is organized as a corporation; and (2) a partner in a disclosing entity that is organized as a partnership.

a. Officers/Directors

i. Corporations Only

For purposes of Part 455, Subpart B, persons with ownership or control of a disclosing entity includes "officers" and "directors" only if the disclosing entity is organized as a corporation. This includes for-profit corporations, non-profit corporations, closely-held corporations, limited liability corporations, and any other type of corporation authorized under state law.

ii. Board Members

In this context, the term "director" refers to members of the board of directors of a corporation. If a corporation has, for instance, a Director of Finance who is not a member of the board of directors, he/she would not need to be disclosed as a director/board member. However, as discussed in section C., below, to the extent he/she meets the definition of "managing employee" under § 455.101; he/she would have to be disclosed as a "managing employee."

iii. Numbers/Volunteers

<u>All</u> officers and directors must be disclosed, regardless of their number (e.g., 100 board members) and even if they serve in a voluntary (e.g., unpaid) capacity. Also, if a non-profit corporation has "trustees" instead of officers or directors, these trustees must be disclosed.

iv. Indirect Levels

Only officers and directors of the disclosing entity, fiscal agent, or managed care entity must be disclosed as such. Officers and directors (e.g., board members) of the entity's indirect owners need not be disclosed as such. However, there may be situations where the officers and directors/board members of the enrolling provider's corporate owner/parent also serve as the enrolling provider's officers or directors/board members. In such cases — and again assuming that the provider is a corporation — the indirect owner's officers or directors/board members would have to be disclosed as persons with ownership or control interests in the provider.

- b. Partners
- i. General and Limited Partnership Interests

All general and limited partnership interests must be disclosed, regardless of the percentage.

ii. Limit on Partnership Interest Disclosure

Only partnership interests in the disclosing entity need be disclosed. Partnership interests in the entity's indirect owners need not be reported. However, if the partnership interest in the indirect owner results in a greater than 5 percent indirect ownership interest in the disclosing entity, this indirect ownership interest must be disclosed.

c. Disclosure by Individuals in Other Capacity

It is important to remember that although an individual or entity may not qualify as an officer, director, or partner and need not be disclosed as a person with an ownership or control interest in the disclosing entity, the party may have to be disclosed in another capacity. Using our earlier example concerning the Director of Finance, he/she may not be a corporate officer or director/board member; however, if he/she qualifies as an owner or managing employee (see section 1.4.1.C.1.d "Managing Employee Disclosure") he/she would have to be disclosed.

D. When Disclosure Is Required (§ 455.104(c))

Under § 455.104(d), all disclosures must be provided to the SMA, and under § 455.104(e), FFP is not available in payments made to a disclosing entity that fails to disclose ownership or control information as required by § 455.104. In addition, please refer to Section 1.10 "Terminations" for a discussion regarding the SMA's requirements, under § 455.416, to terminate any provider where the provider or a person with a 5 percent or greater direct or indirect ownership interest in the provider does not submit timely and accurate information (such a termination would be considered "for cause").

1. Providers or Other Disclosing Entities (§ 455.104(c)(1))

Disclosure from any provider or other disclosing entity is due at any of the following times:

- Upon the provider or other disclosing entity submitting the provider application
- Upon the provider or other disclosing entity executing the provider agreement
- Upon request of the SMA during revalidation under § 455.414

Within 35 days after any change in ownership of the disclosing entity

2. Fiscal Agents (§ 455.104(c)(2))

Disclosures from fiscal agents are due at any of the following times:

- Upon the fiscal agent submitting the proposal in accordance with the state's procurement process
- Upon the fiscal agent executing the contract with the state
- Upon renewal or extension of the contract
- Within 35 days after any change in ownership of the fiscal agent

3. Managed Care Entities (§ 455.104(c)(3))

Disclosures from managed care entities (MCOs, PIHPs, PAHPs and Health Insuring Organizations), except PCCMs, are due at any of the following times:

- Upon the managed care entity submitting the proposal in accordance with the state's procurement process
- Upon the managed care entity executing the contract with the state
- Upon renewal or extension of the contract
- Within 35 days after any change in ownership of the managed care entity

4. PCCMs (§ 455.104(c)(4))

PCCMs must comply with the disclosure requirements applicable to providers or disclosing entities, as described above.

1.4.2 Business Transactions (§ 455.105)

Under § 455.105(a), A Medicaid agency must enter into an agreement with each provider under which the provider agrees to furnish to it or to the Secretary on request, information related to business transactions in accordance with 455.105(b).

Under § 455.105(b), a provider must submit, within 35 days of the date of a request by CMS or the SMA, full and complete information about—

- The ownership of any subcontractor with whom the provider has had business transactions totaling more than \$25,000 during the 12-month period ending on the date of the request (§ 455.105(b)(1)); and
- Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request (§ 455.105(b)(2)).

Per § 455.105(c), FFP is not available in expenditures for services furnished by providers that fail to comply with a request made by CMS or the SMA under § 455.105(b) or under 42 CFR § 420.205; FFP will be denied in expenditures for services furnished during the period beginning on the day following the date the information was due to CMS or the SMA and ending on the day before the date on which the information was supplied. In addition, please refer to Section 1.10 "Terminations" for a discussion regarding the SMA's requirements, under § 455.416, to terminate any provider where the provider or a person with a 5 percent or greater direct or indirect ownership interest in the provider does not submit timely and accurate information and cooperate with any screening methods required under 455 Subpart E (such a termination would be considered "for cause").

1.4.3 Criminal Convictions (§ 455.106)

Under § 455.106, all providers are subject to the SMA's requirement to disclose the identity of certain persons with criminal convictions (see Section 1.4.3.A below). This provision differs from the criminal background check requirement at § 455.434. Under § 455.434, the SMA is required to require certain persons to consent to criminal background checks and submit a set of fingerprints upon request, for the purpose of conducting a criminal background check. See 1.5.4 "Screening Activities by Category" and 1.5.5.4 "Fingerprinting/Criminal Background Checks" for additional discussion of these requirements.

A. General Disclosure Requirements (§ 455.106(a))

Under § 455.106(a), the provider must disclose to the SMA any individual who meets both of the following requirements:

 Has ownership or control interest in the provider, or is an agent or managing employee of the provider; and Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or Title XX (Social Services), since the inception of those programs.

This information must be disclosed before the SMA enters into or renews a provider agreement, or at any time upon the SMA's written request.

B. Notification to Inspector General (§ 455.106(b))

Under § 455.106(b):

- The SMA must notify the OIG of any disclosures made under § 455.106(a) within 20 working days from the date it receives the information.
- The SMA must also promptly notify the OIG of any action it takes on the provider's application for participation in the program, whether approval or disapproval.

C. Denial/Termination

Under § 455.106(c):

- The SMA may refuse to enter into or renew an agreement with a provider if any
 person who has an ownership or control interest in the provider, or who is an agent
 or managing employee of the provider, has been convicted of a criminal offense
 related to that person's involvement in any program established under Medicare,
 Medicaid, or Title XX.
- The SMA may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under § 455.106(a).
- 1. Additional Regulatory Authority for Denials/Terminations under 455 Subpart E

This section covers the regulatory authority available under 455 Subpart B for a SMA to refuse to enter into a provider agreement. Additional authorities are provided for a SMA to deny or terminate a provider agreement under 455 Subpart E. Refer to § 455.416 and Section 1.9 "Denials" and 1. 10 "Terminations" of this compendium.

2. Regulatory Authority to Set Reasonable Standards Relating to the Qualifications of Providers

Under § 431.51(c)(2), the State Medicaid Plan has the authority to set reasonable standards relating to the qualifications of providers.

1.5 Enrollment and Screening – General Requirements (§ 455.410(a))

Under § 455.410, the SMA:

- (a) Must require all participating providers to be screened in accordance with the requirements of §§ 455.412 through 455.450.
- (b) Must require all ordering or referring physicians or other professionals, who order or refer items or services for Medicaid beneficiaries under the state plan or under a waiver of the plan to be enrolled as participating providers.
- (c) May rely on the results of the provider screening performed by any of the following:
 - (1) Medicare contractors
 - (2) Medicaid agencies or Children's Health Insurance Programs of other states

A. Screening by Medicare or its Contractors

Under § 455.410(c)(1) "Medicare contractors" can include screening by either CMS or its contractors.

B. Delegating Screening to Third Parties

A SMA may, but is not required to, delegate screening activities required under 455 Subpart E to third parties, including networks. (See section 1.4.1.A.1.a. for limitations on delegating the collection of disclosures under Subpart B). In the event the SMA opts to delegate screening under Subpart E, the SMA should make sure third parties are carrying out activities consistently and should make sure redundant screening is not conducted for a provider participating in multiple networks. In addition, the SMA should make sure the third party is documenting screening. Also refer to Section 1.5.3.B.1 "SMA Bears Responsibility for Screening Activities Delegated to its Contractors."

For those states delegating screening activities to third party entities, the State should consider any conflicts of interest that may arise. For example, some managed care entities (MCEs) may have delegated credentialing agreements that allow providers to "credential themselves" and submit the appropriate certification needed to participate in a MCE plan. Once the provider attests and submits they have completed all credentialing requirements, the MCE determines whether they will approve of the provider's participation in the plan. This arrangement is not permissible in complying with the screening requirements at 455 as it not only creates a conflict of interest but also we do not believe it allows the state to maintain appropriate oversight of the screening activities.

1.5.1 Enrollment Requirements for Specific Provider Categories

The requirements at 42 CFR part 455, subparts B and E are applicable to all provider types eligible to enroll as participating providers in the state's Medicaid program as it is integral to the integrity of the Medicaid program that all providers that order, refer or furnish services to Medicaid beneficiaries are appropriately screened and enrolled.

A. Fee for Service and Network Providers

1. Fee for Service Providers

Under 455 Subparts B and E, SMAs must screen and, enroll, and periodically revalidate, all feefor-service providers. These provisions do not require providers that order or refer services to Medicaid beneficiaries to also furnish services. See 1.1.A.3 "Applicability to Fee For Service Providers."

2. Network Providers

Effective January 1, 2018, providers under all service delivery models, may furnish services to Medicaid beneficiaries, including as ORPs, only where the state has executed a provider agreement with the provider and performed all applicable screening, unless an exception applies as described herein. See 1.1.A.4 "Applicability to Network Providers."

B. Ordering or Referring Physicians or Other Professionals (ORP)

1. When the SMA Must Enroll ORPs

The definition of ORP is covered in Section 1.3.

Under § 455.410(b), the SMA must require all ordering or referring physicians or other professionals providing furnishing services under the State plan or under a waiver of the plan to be enrolled as participating providers.

Under this provision, the SMA must require enrollment by all providers that order or refer services or items for Medicaid beneficiaries that are payable or covered by Medicaid. As discussed below, this requirement only applies to provider types that are eligible to enroll under the State plan.

An individual who is already enrolled in Medicaid as a participating provider does not need to submit a separate application to continue ordering or referring services or items. Conversely, enrollment in Medicaid does not require an ordering or referring physician or other professional to become a rendering provider – i.e., to furnish and bill for services to Medicaid beneficiaries.

Please refer to section 1.6 "Claims Processing" for a discussion of the requirement to deny claims that do not carry the NPI of the ORP as required under § 455.440.

a. Enrollment of Out-of-State Ordering or Referring Physicians or Other Professionals (ORPs)

Regarding services furnished out of state, under federal regulation § 435.930(c), state Medicaid agencies must furnish Medicaid promptly without delay, to all eligible individuals, and make arrangements to assist applicants and beneficiaries to get emergency medical care whenever needed.

Further, under § 431.52, the state Medicaid agency must pay for services furnished in another state to the same extent it would pay for services furnished within its boundaries if the services are furnished to a beneficiary who is a resident of the state, under conditions including and not limited to emergency services and services that are more readily available in another state.

Except as described in 1.5.1.B.2 below, SMAs must require all ordering or referring physicians or other professionals (ORPs) to be enrolled as participating providers in order for claims for items or services based on their orders or referrals to be paid. All claims for payment for items and services that were ordered or referred must contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred the item or service (see section 1.6.A.). The requirements to enroll ORPs and deny claims that do not have the NPI of an enrolled ORP applies equally to in-state and to out-of-state ORPs and claims. The requirements described in this paragraph are effective, with respect to fee-for-service claims, beginning March 25, 2011; and with respect to claims under all non-FFS network plans, beginning January 1, 2018.

As discussed in Section 1.5.3.B.3.d, the SMA may, but is not required to, rely on provider screening performed by another state's Medicaid Program.

As discussed in Section 1.5.3.a. and 1.5.3.c, the SMA may, but is not required to, rely on provider screening performed by Medicare.

If the SMA opts not to rely on screening performed by either another state's Medicaid or by Medicare, the SMA must perform screening in compliance with the requirements at Subpart E.

b. Enrollment of Veterans Administration (VA) or Indian Health Services (IHS) Providers

The requirement to enroll ORP providers and deny claims that do not have the NPI of an enrolled ORP applies equally to providers without respect to their employer, to the extent the claim does not qualify for an exception under 1.5.1.B.2. "When the SMA is not Required to Enroll ORPs."

Example: A Medicaid beneficiary receives services from a provider employed by, for example, a VA or IHS facility. If the VA or IHS physician/professional orders or refers the beneficiary

additional services or items payable by Medicaid FFS, that ORP must be enrolled in the beneficiary's State Medicaid Plan in order for the claim for the ordered or referred items or services to be paid.

c. Enrollment of Contracted Hospitalists or Emergency Room Physicians

Many Medicaid-enrolled hospitals employ hospitalists or contracted emergency room physicians who are not separately enrolled as Medicaid providers. Services/items/prescriptions that are ordered/referred/written by these hospitalists/contracted physicians are ineligible for payment unless the hospitalist/physician is enrolled in Medicaid, to the extent the claim does not qualify for an exception under 1.5.1.B.2. "When the SMA is not Required to Enroll ORPs."

- 2. When the SMA is not Required to Enroll ORPs
- a. ORPs Ineligible to Enroll in a Particular State's Medicaid Program

To the extent a provider type is not eligible to enroll in a State's Medicaid Program, the SMA is not required to begin to enroll that provider type for purposes of complying with §§ 455.410(b) or 455.440. For example, in some states, professionals, such as residents, function under a scope of practice that authorizes them to order or refer, but they are not eligible to enroll in Medicaid. States must determine which NPI number should be applied to the claim for payment if such providers order or refer services for Medicaid or CHIP beneficiaries, and the SMA should notify providers of its requirements.

In a situation where an ordering or referring physician or other professional is eligible to enroll in the state's Medicaid Program, it is not permissible to submit claims with an organizational NPI appearing in place of that individual's NPI. For example, if a hospital submits a claim with the hospital's NPI in the ordering/referring field and the services were ordered or referred by a provider type that is eligible to enroll in the state's Medicaid Program, the claim is not compliant under § 455.440 and must be denied.

b. Medicaid Beneficiary Secures Order or Referral Prior to Participation

To the extent an order or referral is made to an individual prior to that individual's eligibility to participate in Medicaid, such order or referral may be fulfilled and the pursuant claim is not require to be denied based upon the requirements for the ORP to be enrolled in Medicaid and the individual ORP's NPI to appear on the claim. (76 FR 5905)

c. Services Ordered or Referred by Out-of-State Professional

Under federal regulations, State Medicaid agencies (SMAs) must require all ordering or referring physicians or other professionals (ORPs) to be enrolled as participating providers (see section 1.5.1.B.). In addition, all claims for payment for items and services that were ordered or

referred must contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred the item or service (see section 1.6.A.). The requirements to enroll ORPs and deny claims that do not have the NPI of an enrolled ORP applies equally to in-state and to out-of-state ORPs.

However, for claims representing care or items (including, but not limited to, prescription drugs) provided to a beneficiary pursuant to the order or referral made by an out-of-state ORP, the SMA may pay such claims where the ORP is not enrolled in the reimbursing state's Medicaid plan, in limited circumstances. Such claims qualify for FFP only to the extent that they are otherwise payable and meet all of the following criteria:

- Based upon an order or referral, an item or service is furnished by:
 - An institutional provider at an out-of-state practice location—i.e., located outside the geographical boundaries of the reimbursing state's Medicaid plan, or
 - An individual practitioner in an institutional setting at an out-of-state practice location— i.e., located outside the geographical boundaries of the reimbursing state's Medicaid plan, or
 - A pharmacy, pursuant to an order (i.e., prescription) written by an individual practitioner in an institutional setting at an out-of-state practice location—i.e., located outside the geographical boundaries of the reimbursing state's Medicaid plan.
- The NPI of the ORP is represented on the claim;
- The ORP is enrolled and in an "approved" status in Medicare or in another state's Medicaid plan; and
- The claim represents services provided
- The claim represents services covered under the state plan
- The claim represents either
 - o A single instance of care or order over a 180 day period, or
 - Multiple instances of care provided to a single beneficiary, over a 180 day period.

For any instances of care that exceed the thresholds above, the SMA must enroll the ORP in the state Medicaid plan for subsequent claims to be FFP-eligible.

Example: A beneficiary receives services from an out-of-state emergency room or hospital, and a physician or other professional at the emergency room or hospital writes a prescription upon discharge. That physician/professional must be enrolled (either as a rendering provider or as an ordering or referring one) in the Medicaid Program in which the beneficiary is enrolled in order

for the beneficiary's State Medicaid Plan to cover the ordered/referred service/item. Otherwise, the claim is eligible for FFP only to the extent the following conditions are met: the NPI of the ORP is listed on the prescription; the ORP, if they were to enroll in the reimbursing state Medicaid Plan, would enroll with an out of state practice location; the ORP is enrolled in Medicare or another state's Medicaid plan in an "approved" status; and there has not been more than one instance of payment made (irrespective of eligibility of payments for FFP) representing a claim for services ordered or referred by that provider's NPI over a 180 day period, or, if there are multiple instances of payment made for benefits ordered or referred by that provider's NPI over a 180 day period, that the payment is for a single beneficiary over a 180 day period.

C. Furnishing Providers

1. When the SMA Must Enroll Furnishing Providers

In general, furnishing providers are required to be enrolled. This requirement is based upon § 1902(a)(78) of the Act, which requires "each provider furnishing items and services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable).

- 2. When the SMA is not Required to Enroll Furnishing Providers
- a. Limited Exception for Services Furnished by Providers Out-of-State

Regarding services furnished out of state, under federal regulation § 435.930(c), state Medicaid agencies must furnish Medicaid promptly without delay, to all eligible individuals, and make arrangements to assist applicants and beneficiaries to get emergency medical care whenever needed. Further, under § 431.52, the state Medicaid agency must pay for services furnished in another state to the same extent it would pay for services furnished within its boundaries if the services are furnished to a beneficiary who is a resident of the state, under conditions including and not limited to emergency services and services that are more readily available in another state.

As described in Section C.1. above, a SMA generally must enroll furnishing providers. For claims representing care furnished to a beneficiary by an out-of-state furnishing provider, the SMA may pay a claim to a furnishing provider that is not enrolled in the reimbursing state's Medicaid plan, in limited circumstances. Such claims qualify for FFP only to the extent that they are otherwise payable and meet the following criteria:

- The item or service is furnished by an institutional provider, individual practitioner, or pharmacy at an out-of-state practice location—i.e., located outside the geographical boundaries of the reimbursing state's Medicaid plan;
- The NPI of the furnishing provider is represented on the claim;
- The furnishing provider is enrolled and in an "approved" status in Medicare or in another state's Medicaid plan;
- The claim represents services furnished; and
- The claim represents either:
 - o A single instance of care furnished over a 180 day period, or
 - Multiple instances of care furnished to a single beneficiary, over a 180 day period.

For any instances of care that exceed the thresholds above, the SMA must enroll the furnishing provider in the state Medicaid plan for subsequent claims to be FFP-eligible.

Example: A beneficiary receives a complex inpatient service at an out of state hospital. The beneficiary will be treated by multiple providers and the hospital will also bill the beneficiary's home state Medicaid plan for facility fees. Claims are eligible for FFP only to the extent the following conditions are met: the NPI of the furnishing provider is listed on the claim; the furnishing provider, if they were to enroll in the reimbursing state Medicaid Plan, would enroll with an out of state practice location; the furnishing provider is enrolled in Medicare or another state's Medicaid plan and in an "approved" status; and, either there has not been more than one instance of payment made (irrespective of eligibility of payments for FFP) representing a claim for services furnished by that provider's NPI over a 180 day period, or, if there are multiple instances of payment made for services by that furnishing provider's NPI over a 180 day period, that the payment is for a single beneficiary over a 180 day period.

As discussed in Section 1.5.3.B.3.d, the SMA may, but is not required to, rely on provider screening performed by another state's Medicaid Program.

As discussed in Section 1.5.3.a. and 1.5.3.c, the SMA may, but is not required to, rely on provider screening performed by Medicare.

If the SMA opts not to rely on screening performed by either another state's Medicaid or by Medicare, the SMA must perform screening in compliance with the requirements at Subpart E.

1.5.2 When Screening is Required

A. General

Under § 455.450, the SMA must screen all initial applications, including applications for a new practice location, and any applications received in response to a reenrollment or revalidation of enrollment request based on a categorical risk level of "limited," "moderate," or "high." The SMA has substantial discretion in how it performs and completes each required screening activity.

B. Screening Upon New Enrollment

The SMA must screen providers upon receipt of an initial enrollment application and the SMA must complete all screening activities prior to approving the enrollment.

C. Screening for Practice Locations

1. Practice Location - New Enrollment

The SMA conducts full screening upon new enrollment, including a site visit when the provider is categorized as a "moderate" or "high" risk category provider. See 1.5.3 "Site Visits" and 1.5.4 "Screening Activities by Category."

2. Addition of a Practice Location to an Existing Enrollment

If the SMA permits a new practice location to be added under an existing enrollment, when the practice location is added to a "moderate" or "high" risk category enrollment, the SMA must conduct a site visit for the newly added location but a full rescreening of the enrollment is not required.

D. Screening Upon Revalidation

1. Screening upon Receipt of an Application

The SMA must screen providers upon receipt of an application for revalidation.

2. Revalidation Frequency

Consistent with § 455.414, the SMA (beginning March 25, 2011) must complete revalidation of enrollment for all providers, regardless of provider type, at least every five years (this includes ordering or referring physicians or other professionals). The SMA has the discretion to require revalidation on a more frequent basis.

3. Revalidation Screening Appropriate to a Provider's Risk Category

In revalidating a provider's enrollment, the SMA must conduct a full screening appropriate to the provider's risk level. The risk-based screening requirements under § 455.450 that apply to a newly enrolling or reenrolling provider also apply to revalidation. Revalidation includes the disclosure requirements specified in §§ 455.104, 455.105, and § 455.106, and, depending on the provider's risk level, includes site visits and Fingerprint-based Criminal Background Checks (FCBCs).

It is important to note from a claims and PERM perspective that providers who fail to revalidate by their revalidation due date should not receive payments during the gap between the revalidation due date and the date the screening for revalidation is completed as these payments could be cited as improper payments during a PERM review. Payment is only appropriate after screening is completed.

4. Establishing Revalidation Deadlines

As with all revalidations, revalidations described in this paragraph are conducted in accordance with the screening procedures specified at Subpart E.

With respect to establishing revalidation deadlines, 455.414 requires revalidation at least every 5 years, and 455.452 provides that states may establish screening methods "in addition or more stringent than those required by" federal regulations. One such additional screening method might be off cycle revalidations, when warranted. Off cycle revalidations may be triggered as a result of random checks, information indicating local health care fraud problems, national initiatives, complaints, evidence the SMA receives indicating noncompliance with statute or regulations by specific provider types, or other reasons that cause the SMA to question the compliance of the provider or supplier with Medicaid enrollment requirements.

When revalidating a provider, the SMA may rely on Medicare or another state's screening as described in the sections below.

E. Screening upon "Reenrollment" or "Reactivation"

The SMA must screen providers upon receipt of an application for reenrollment or reactivation.

Reenrollment occurs when a provider has been terminated, deactivated, or otherwise removed as a state Medicaid provider and seeks to reestablish/reactivate its enrollment. A reenrollment is essentially a new enrollment; in other words, a SMA reenrolling a provider must follow the same steps that it would if the provider were newly enrolling. The fact that a provider is reenrolling does not lessen the requirements for the SMA to conduct provider screening and enrollment on that provider the same way the state would conduct the screening for any newly enrolling provider.

Reactivation occurs when a provider's enrollment number is deactivated for any reason. As with reenrollment, reactivation requires the SMA to follow the same steps that it would if the provider were newly enrolling. Section 455.420 addresses reactivation of provider enrollment. If a provider's enrollment has been deactivated for any reason and the provider seeks to reactivate its enrollment, the SMA must rescreen the provider using risk-based screening under § 455.450.

F. Screening: Timeliness

CMS does not have a required timeframe for screening a particular application for enrollment, reenrollment, reactivation, or revalidation of enrollment, or for conducting associated activities (e.g., site visit in the case of "moderate" or "high" risk providers). However, the SMA may *not* enroll, reenroll, reactivate, or revalidate the enrollment of a provider until it has completed all of the screening activities applicable to that provider. SMAs are encouraged to avoid unnecessary delays in application screening.

1.5.3 Screening Process (§ 455.450)

For a discussion of the components of screening (site visit, etc.) please refer to section 1.5.5, "Principal Components of Screening."

A. Use of Disclosure Information in Screening

1. Screening Based Upon Disclosures

Under 455 Subpart B, providers disclose information to the SMA. The SMA uses the information collected to conduct some of the required screening activities under Subpart E. For example, the SMA uses the SSNs disclosed to complete the required database checks at § 455.436.

2. Verifying disclosures

As a best practice, CMS recommends screening the information disclosed by an organizational provider under § 455.104 against:

- Any data available from state business licensure boards
- Medicare's enrollment record for the same provider (based upon name and TIN)

a. Reporting to CMS Discrepancies in Ownership

If an organizational provider dually participates in Medicare and a state's Medicaid Plan, the provider is expected to make accurate and consistent disclosures to each program. Medicare

providers disclose information pursuant to federal regulations at §§ 420.202 through 420.206. Providers are required, under § 455.104(b)(1) and § 420.206(a)(1) to disclose information to Medicaid and Medicare, respectively, concerning individuals with a 5 percent or more ownership interest in the provider.

To the extent the SMA is able to use Medicare's enrollment information to verify that the same organization's same ownership has been disclosed to the Medicaid and Medicare Programs, the SMA is able to rely on Medicare's screening of that provider, as long as the other required elements match (see Section 1.5.3. "Screening Process" for more information).

If the SMA is not able to verify the same ownership interest is reflected in Medicare's enrollment record for the same provider, the SMA is generally not able to rely on Medicare's screening. When the SMA discovers ownership interests do not match for the same provider, CMS requests the SMA report such a discrepancy.

The process for the SMA to report an ownership discrepancy to CMS follows:

SMA sends an email to the assigned CMS BFL. This email should include:

- Provider name, TIN, and NPI
- The ownership information (5% or more owners) reported to the SMA
- The date the ownership information was reported to the SMA

CMS will take steps to make sure Medicare providers are disclosing information in compliance with Medicare's requirements, or CMS may respond to the SMA to recommend follow up by the SMA.

3. Form and Manner of SMA's Revalidation

The SMA has the discretion to:

- Require or permit paper and/or on-line revalidation
- Pre-populate revalidation applications
- Use any means it chooses to notify providers to revalidate

B. Other State Screening Methods

1. SMA Bears Responsibility for Screening Activities Delegated to its Contractors

For the provider screening requirements under Subpart E and based on the disclosures under Subpart B, to the extent that a SMA delegates responsibility for provider screening and enrollment to a contractor, the SMA remains fully responsible for compliance with the requirements at Subpart B and Subpart E. For additional information concerning delegating activities to contractors, see Sections 1.4.1.A.1.a "Delegating Collection of Disclosures to a Network Plan" and 1.5.B "Delegating Screening to Third Parties."

2. State Discretion to Apply Higher Risk Level and/or Conduct Additional Activities

Under § 455.452, nothing in Subpart E restricts a SMA from establishing provider screening methods in addition to or more stringent than those required by Subpart E.

For example, a SMA has the discretion to:

- Perform verification activities in addition to (but not in lieu of) those mentioned in Part 455 Subpart E.
- Impose requirements on providers in addition to those outlined in Part 455 Subpart E (assuming they are not inconsistent therewith). For instance, a SMA may require certain providers to obtain liability insurance, have a period of provisional or trial enrollment as a means of ensuring that the provider can remain compliant with state and federal rules, etc.
- Apply a higher screening level than that which Medicare applies. Should a SMA choose to elevate a provider's risk category, all required screening activities according to that category must be completed.
- Conduct additional screening activities beyond what Subpart E requires.
- Conduct required screening activities in a manner more stringent than how Medicare or another SMA conducts the same required screening activity (for example, a more comprehensive site visit).
- 3. Reliance on Screening Performed by Medicare or a State Agency

To rely on Medicare's screening in place of its own, the SMA must verify the following conditions are met:

• The date of Medicare's last screening (revalidation or new enrollment) of the subject provider must have occurred within the last five years, and

- The provider must be the "same" in Medicaid and Medicare. A provider is the same
 when the SMA is able to match the applicable data elements shown in Table 1 under the
 section "Instructions for relying on provider screening conducted by Medicare (42 CFR §
 455.410) or conducting additional screening when required," and
- The Medicare enrollment must be in an "approved" status, and
- The Medicare risk category must equal or exceed the Medicaid risk category for that
 provider with the exception of prospective Home Health Agency or Durable Medical
 Equipment (DME) providers, which Medicare decreases to the "moderate" risk category
 upon successful enrollment.

Please note, this is illustrated by "Scenario 1" under 4 below.

a. Relying on Revalidation Conducted by Medicare

Note: This section discusses revalidation. More general instructions for relying on provider screening conducted by Medicare are found under Section 1.5.3.B.3, above.

Under certain circumstances, the SMA may rely on the screening conducted in connection with Medicare's revalidation or enrollment process in place of its own screening. The SMA remains responsible to collect its own disclosures required under 42 CFR 455 Subpart B; the SMA cannot rely on Medicare to collect disclosures in its stead. The SMA must maintain its own provider agreements. In general, the SMA may rely upon Medicare screening to the extent Medicare has screened the same provider.

When able to rely on revalidation conducted by Medicare, the SMA is not required to collect a revalidation application. Please note the ability to rely on revalidation and/or screening conducted by Medicare is subject to the section "Instructions for relying on provider screening conducted by Medicare (42 CFR § 455.410) or conducting additional screening when required."

b. Required Database Checks Under § 455.436

Ongoing Monthly Database Checks – Reliance on Medicare

The SMA may rely on the new enrollment or revalidation screening conducted by Medicare or another State, but the SMA may not rely on Medicare or another State's Medicaid Plan to fulfill its own ongoing monthly database checks required under § 455.436(c)(2).

4. Instructions for Relying on Provider Screening Conducted by Medicare (42 CFR § 455.410) or Conducting Additional Screening When Required

Under federal regulations at § 455.410, SMAs must require all enrolled providers to be screened based on the level of risk of fraud, waste, or abuse to the State Medicaid Plan. In conducting risk-based screening of providers enrolled in both Medicare and Medicaid, SMAs may, but are not required to, rely on the results of screening performed by Medicare or its contractors.

All references to Medicare screening are inclusive of screening by Medicare's contractors. This guidance describes how a SMA may rely on Medicare's screening. The SMA may rely upon the results of a provider screening performed by Medicare (§ 455.410(c)(1)) using one of the following scenarios:

Scenario 1: Relying on an "approved" Medicare status without verifying each screening activity

To rely on PECOS in this scenario, the SMA verifies:

- A positive match (defined in the "Positive Match" section below) of the provider applying for Medicaid enrollment against the information in Medicare's enrollment record, and
- An "approved" Medicare enrollment status, and
- Medicare's screening risk category for the provider (i.e., "limited," "moderate" or "high"), with the exception of HHA, DMEPOS, MDPP or OTP providers, which Medicare decreases to the "moderate" risk category upon successful enrollment, and
- The date of Medicare's most recent revalidation occurred within the last 5 years.

Under Scenario 1, the SMA can rely on Medicare's screening to include all screening activities up to and included in a particular risk category, regardless of whether Medicare's enrollment record reflects a particular activity was completed. Relying on Medicare's screening always includes the ability to rely on Medicare's licensure and database checks. A SMA that relies on Medicare's screening as described below is compliant with the screening requirements under 455 Subpart E.

<u>Scenario 2</u>: SMA verifies that discrete screening activities are reflected in Medicare's enrollment records

To rely upon Medicare's screening activity in scenario 2, the SMA verifies, for an individual or organizational provider:

- A positive match of a provider applying for Medicaid enrollment against the information in a Medicare enrollment record, and
- An "approved" Medicare enrollment status, and
- The Medicare enrollment record reflects a specific required screening activity that occurred within the last 5 years.

If the SMA is not able to verify a positive match by comparing each of the required data elements in Table 1, below, the SMA may nonetheless rely on Medicare site visits performed for approved Medicare enrollments at locations matching the information on file in Medicaid, provided the site visit was conducted for the same business (matching business name) with a matching tax identification number.

To rely on Medicare's FCBC result of a 5 percent or more owner under scenario 2, the SMA verifies:

- A positive match of the 5 percent or more owner applying for Medicaid enrollment within any Medicare enrollment record, and
- The enrollment record listing the 5 percent or more owner is in an "approved" status, and
- The Medicare enrollment record reflects the FCBC with a "Completed PASS" result.

Under scenario 2, the SMA can rely on individual screening elements Medicare has completed to the extent those activities are reflected as completed in the Medicare enrollment record.

Table 1: Minimum Required Data Elements to Compare

	Risk	Name ¹	NPI	SSN ²	TIN	Practice	All 5% or
	Category			(Last 4		Location(s)	more
				digits)			owners ²
Individual	"Limited"	Χ	Χ	Χ			
Provider	"Moderate"	Χ	Χ	Χ		Х	
	"High"	Χ	Χ	Χ		Χ	
Organizational	"Limited"	Χ			Χ		Χ
Provider	"Moderate"	Χ			Χ	Х	Χ

"High" ^{3, 4}	Χ		Χ	Χ	X

¹ The SMA will use its discretion to determine a name match (i.e. John W. Smith vs. John Wilkes Smith.)

In order to rely upon Medicare's screening, the SMA must make a positive match of the provider applying for Medicaid enrollment against the information in PECOS. Under § 455.452, the SMA can establish methods in addition to or more stringent than those required herein.

To confirm a match, the SMA should use the Table 1 above to identify which data elements are minimally required to match based on provider types and provider risk screening levels. An "X" in the table designates minimum data elements that must match in PECOS for the SMA to consider the provider a positive match. Only when a provider is a positive match may a SMA use the "approved" status and risk category (i.e. "limited," "moderate" or "high") information, excluding DME, HHA, MDPP and OTP providers, to determine whether it can rely on Medicare's screening as described in the two scenarios above.

"Approved" Medicare enrollment status

The subject provider must be active in Medicare, as indicated by an "approved" Medicare enrollment status.

Medicare accreditation and Medicare certification are not substitutes for "approved" Medicare enrollment status. For more information, refer to "Selected Definitions" under Section 1.1.2.

Risk category confirmation

The SMA must verify the risk category for a provider's Medicare enrollment.

Because a risk screening category corresponds to a list of required screening activities for that category, once the SMA confirms the information above, it may rely on Medicare to complete all screening requirements that correspond to the particular risk category. For example, if a

² For individual providers and each 5 percent or more owner, the SMA must confirm a positive match by comparing name and last 4 digits of SSN.

³ In Medicare, newly enrolling "high" risk providers (HHA, DMEPOS, *MDPP and OTP*) subsequently drop to the "moderate" risk category upon successful Medicare enrollment therefore SMAs are not required to match the risk category for these providers.

⁴ For Medicaid DME providers, the SMA must ensure they are comparing the Medicaid application to the <u>855S</u> DMEPOS Supplier Medicare enrollment record found in PECOS.

provider is in a Medicare "moderate" risk screening category, the SMA may rely on an "approved" enrollment status to fulfill all of its own required screening activities up to and including all those activities that correspond to the "moderate" risk category, regardless of whether or when Medicare conducted the screening activities.

If a SMA enrolls a Medicaid provider in a screening category that exceeds Medicare's, the SMA must either confirm Medicare or another state has performed the required screening activity based on the incremental increase in risk category or the SMA must itself conduct that incremental screening activity, as indicated in Table 2 below. For example, if a Medicare "moderate" risk provider is enrolled in Medicaid in a "high" risk category, the SMA must confirm Medicare or another state has conducted the additional screening required for a provider in a "high" risk screening category (in this case, an FCBC) or else the SMA must conduct the FCBC itself.

If a SMA is processing a new enrollment for a DME, HHA, *MDPP or OTP* provider, the state is not required to match the risk category when the Medicaid risk category exceeds Medicare's as noted under Table 1 above.

Table 2: Risk Category Differences that Require the SMA to Conduct Additional Screening

Medicaid Risk	Medicare Risk	SMA required to conduct additional
Category	Category	Screening
"Limited"	"Limited"	None
"Limited"	"High"*	None
"Moderate"	"Limited"	State must conduct: Site Visit
"Moderate"	"Moderate"	None
"Moderate"	"High"	None
"High"	"Limited"	State must conduct: Site Visit and FCBC
"High"	"Moderate"	State must conduct: FCBC
"High"	"High"	None

^{*} Note: this scenario would mainly occur when Medicare imposes a payment suspension on a provider which demands Medicare bump that provider up under § 424.518; however, a State Medicaid Plan is not required to bump providers up to "high" risk based on Medicare payment suspensions.

Examples:

Example 1. The SMA receives a new enrollment application from an individual provider. The provider is in a "limited" risk category and is in an "approved" PECOS status. The SMA confirms

the provider's name, NPI, and last 4 digits of SSN match with what is in PECOS. The SMA may rely on Medicare's screening activities that correspond to the "limited" risk category.

Example 2. The SMA receives a revalidation application from a home health agency. The SMA revalidates its HHA organizational providers in the "moderate" risk category (as does Medicare). Using the table above, the SMA compares the following data elements in PECOS to establish a positive match: Name, TIN, Practice Location(s), and 5 percent or more owners.

Because the subject HHA is "approved" in PECOS and the SMA confirms the data elements match between the Medicaid application and PECOS, the SMA is able to rely on Medicare's screening to fulfill its own screening requirements. Because the provider is an HHA provider, the SMA is exempt from having to confirm a match on risk category in PECOS. The SMA would not collect an application fee from the HHA.

Example 3. The SMA receives a new enrollment application for a DME provider. The SMA enrolls new DME organizational providers in the "high" risk category. Using the table, the SMA compares the following data elements to PECOS to establish a positive match: Name, TIN, Practice Location(s), and 5 percent or more owners. The SMA determines the DME is "approved" in PECOS. The SMA also determines the DME is categorized as "moderate" risk in PECOS because Medicare has already screened and enrolled the provider. Because the provider is a DME provider, the SMA is exempt from having to confirm a match on risk category in PECOS.

5. Instructions for Relying on Provider Screening Conducted by Another State's Medicaid Program (§ 455.410(c)(2)) or Conducting Additional Screening When Required

The SMA may, but is not required to, rely on provider screening performed by another state's Medicaid Program. Specifically, under § 455.410(c), if a provider is enrolled and in good standing with another state's Medicaid Program, the SMA may rely on that enrollment to meet the screening and enrollment requirements (§ 455.410(a)) including those for ordering or referring providers (§ 455.410(b)).

When relying on another State's Medicaid Plan, the SMA must:

- Verify the provider is the "same." A provider is the same when the SMA is able to match
 the applicable data elements shown in Table 1 under the section "Instructions for relying
 on provider screening conducted by Medicare (42 CFR § 455.410) or conducting
 additional screening when required."
- Document that it confirmed the other state's Medicaid Program performed each required screening activity.
- Confirm the provider is in an approved enrollment status.

 Confirm the most recent date the other state's Medicaid Program enrolled or revalidated the subject provider. If the other state did not enroll or has not revalidated the provider within the previous five years, the SMA may not rely on screening of that provider conducted by the other state's Medicaid Program.

The enrolling SMA bears the responsibility to fulfill any screening activities required to satisfy its own requirements to enroll a provider based on that provider's risk level at the time of enrollment or revalidation. For example, if a SMA is enrolling a provider in a "high" risk category, and another state has already enrolled the same provider but did not conduct an FCBC, it is not appropriate to make a request to the other state that they conduct an FCBC. It is the responsibility of the enrolling agency to conduct any additional screening activities required to fulfill any outstanding screening activities.

A SMA is not required to rely on screening activities performed by another state's Medicaid Program, and may instead choose to conduct its own. Nonetheless, if a SMA chooses to rely on a screening activity conducted by another state's Medicaid Program, there is no requirement for the SMA to evaluate how a particular activity was conducted by another state's Medicaid Program, in order to rely on it. For example, if a SMA confirms another state's Medicaid Program conducted a site visit, but the SMA learns the other state's site visit is comprised of a set of activities that are determined to be less stringent than the SMA's own site visit activities, the SMA may nonetheless rely on that other state's site visit to fulfill its own requirement to conduct a site visit. The regulations at Subpart E leave wide discretion to the SMA in how it chooses to conduct screening activities that fulfill the requirements, keeping in mind the purpose for the requirements are to mitigate the risk of improper payments based on fraud, waste, and abuse.

Example 1. The SMA in State A receives a new enrollment application from a DME provider. State A's SMA finds that it is unable to rely on Medicare's FCBC; therefore, State A must conduct the FCBC. Because the DME provider is based in another State (State B), State A reaches out to State B's SMA. State B's SMA confirms that the DME's enrollment pre-dated the August 1, 2015 FCBC requirement's effective date, and the provider is enrolled in State B as a "moderate" risk category provider. Because State B confirms no "high" risk screening activity was conducted for the DME enrollment, State A must therefore impose and conduct the FCBC requirement on all 5 percent or more owners of the newly enrolling DME.

1.5.4 Screening Activities by Category

A. Required Screening Activities in Subpart E

Required screening activities are based on a provider's risk category, as follows:

1. "Limited" Categorical Risk (§ 455.450(a))

For providers in the "limited" risk category, the SMA must:

- Verify that the provider meets any applicable federal regulations or state requirements for the provider type prior to making an enrollment determination. (§ 455.450(a)(1))
- Conduct license verifications, including state licensure verifications in states other than where the provider is enrolling, in accordance with § 455.412. (§ 455.450(a)(2))
- Conduct database checks on a pre- and post-enrollment basis to ensure that
 providers initially meet and continue to meet the enrollment criteria for their
 provider type, in accordance with § 455.436. (§ 455.450(a)(3))

2. "Moderate" Categorical Risk

For all providers in the "moderate" risk category, the SMA must:

- Perform the "limited" screening requirements described in § 455.450(a). (§ 455.450(b)(1))
- Conduct on-site visits in accordance with § 455.432. (§ 455.450(b)(2))
- 3. "High" Categorical Risk (§ 455.450(c))

For providers in the "high" risk category, the SMA must:

- Perform the "limited" and "moderate" screening requirements described in (§ 455.450(a) and (b). (§ 455.450(c)(1))
- Conduct a criminal background check. (§ 455.450(c)(2)(i))
- Require the submission of a set of fingerprints in accordance with § 455.434. (§ 455.450(c)(2)(ii))
- a. Providers Elevated to "High" Risk under § 455.450(e)

The SMA is required to elevate a provider's screening category in certain circumstances as described in Section 1.3.D, "Risk Levels for Provider Types Also Existing in Medicare." The SMA must conduct any additional required screening upon increasing the risk level. For example, a SMA should not bump a provider up to a "high" risk screening category and also wait until that

provider's next scheduled revalidation to conduct an FCBC. Upon bumping a provider to "high" risk, the SMA must, within 90 days:

- Notify the "high" risk provider that they are subject to the FCBC requirement;
- Collect fingerprints and use the fingerprints to verify whether the provider has a state or national criminal history;
- Take any necessary termination action based on the criminal history data, or document
 in writing why that termination is not in the best interest of the Medicaid Program
 (documentation must be made upon the state's determination to not terminate.
 "Upon" is defined here as within 60 days of the provider's noncompliance and the
 SMA's decision to retain the provider); and,
- Update the provider's enrollment record to reflect FCBC status.

Note that an approved CMS FCBC Compliance plan under 2016-002, "Sub Regulatory Guidance for State Medicaid Agencies (SMA): Fingerprint based Criminal Background Checks (FCBC), supersedes the guidance in this section. The guidance in this section is in force upon the date that the State Medicaid Plan is expected to be in full compliance under the CMS approved FCBC compliance plan.

1.5.5 Principal Components of Screening

1.5.5.1 Licensure Review

Under § 455.412, the SMA must:

- Have a method for verifying that any provider purporting to be licensed in accordance with state law is licensed by said state, and
- Confirm that the provider's license has not expired and that there are no current limitations on the provider's license in any state in which the provider is licensed.

1.5.5.2 Federal Database Reviews

A. Compliance

Under § 455.436, the SMA must do all of the following:

- Confirm the identity and determine the exclusion status of providers and any person with an ownership or control interest or who is an agent or managing employee of the provider through routine checks of federal databases. (§ 455.436(a))
- Check the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE) or the Medicare Exclusion Database (MED), the Excluded Parties List System (EPLS) (now known as the System for Award Management (SAM)), and any such other databases that CMS may prescribe through regulation. (§ 455.436(b))
- Consult appropriate databases to confirm identity upon enrollment and reenrollment. (§ 455.436(c)(1))
- Check the LEIE and SAM no less frequently than monthly. (§ 455.436(c)(2))

The LEIE has both an online searchable database and a downloadable format. Both databases may be accessed directly on the HHS-OIG website at: http://oig.hhs.gov/exclusions/index.asp. CMS has also processed the LEIE into an equivalent database - the MED - which some SMAs have found easier to search. Currently, SMAs can download the MED files via the Data Exchange System (DEX).

The purpose of the monthly checks of the LEIE/MED and SAM/EPLS under § 455.436(c)(2) is to ensure that enrolled providers, and any person with an ownership or control interest or who is an agent or managing employee of the provider has not been excluded from Medicare or Medicaid and has not been excluded from receiving federal contracts. *CMS recommends but does not require States to instruct their providers and MCEs to check their own employees and contractors for exclusions against the LEIE/MED at the time of hiring and on a monthly basis as outlined in the State Medicaid Director's Letter number 09-001 (https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD011609.pdf)*

SMAs shall deny the enrollment of newly enrolling providers, if any provider and any person with an ownership or control interest or who is an agent or managing employee of the provider is found on the LEIE/MED or SAM/EPLS. The SMA shall terminate the enrollment of enrolled providers and report the termination to CMS, if any provider and any person with an ownership or control interest or who is an agent or managing employee of the provider is found on the LEIE/MED or SAM/EPLS.

As described in Section 1.5.3.B.3.b "Required database checks under § 455.436," the SMA may not rely on Medicare or another state's Medicaid Program to fulfill its own monthly database checks required under § 455.436(c)(2).

B. Exceptions

1. Providers Ineligible for an National Provider Identifier (NPI)

See 1.1.2.B. "Other Definitions and Terms" for a discussion of the NPI. To the extent a provider *or provider type* is ineligible to apply for a NPI but is enrolled in a state Medicaid Program, the NPPES database check would not apply.

1.5.5.3 Site Visits

A. Site Visits: General

Under § 455.432, the SMA must:

- Conduct pre-enrollment and post-enrollment site visits of providers that are
 included in the "moderate" or "high" screening levels in Medicaid. The purpose of
 the site visit is to verify that the information submitted to the SMA is accurate and to
 determine compliance with federal and state enrollment requirements. (§
 455.432(a))
- Require any enrolled provider to permit CMS, its agents, its designated contractors, or the SMA to conduct unannounced on-site inspections of any and all provider locations. (§ 455.432(b))

B. Site Visits: Risk-Based Screening

The conduct of on-site visits is one element of compliance of the risk-based screening requirement under § 455.450. Under § 455.450(b)(2) and (c)(1), the SMA must conduct on-site visits in accordance with § 455.432 when screening providers that the agency has designated as "moderate" or "high" categorical risk.

1. Combining Site Visits

Site visits that comply with § 455.432 may be combined with other site visit activity such as those for State Licensing, Survey and Certification and Clinical Laboratory Improvement Act requirements so long as the verification activity for screening and enrollment is documented separately.

2. Site Visits: Announced versus Unannounced

A site visit that complies with § 455.432 is **not** required to be conducted unannounced, although States must require enrolled providers to permit unannounced on-site inspections.

C. Site Visits: Provider Fails to Permit Access

Under § 455.416(f), the SMA must terminate or deny enrollment if the provider fails to permit access to a location for a site visit under § 455.432, unless the SMA determines that termination or denial is not in the State Medicaid Program's best interests and documents that determination in writing.

D. Site Visits: Physical Therapists in Private Practice

- Under § 424.518, physical therapists in private practice are in the "moderate" screening category for Medicare enrollment purposes and are thus subject to site visits as part of their screening.
- If an entity is enrolled or enrolling as a "limited" risk provider (i.e. physician practice, clinic, etc.) and employs a physical therapist within the practice, the entity is not subject to the site visit requirement because the practice itself falls within the "limited" risk screening category (unless the state determines otherwise or the entity's risk status is adjusted upward).
- If a physical therapist is reassigning their benefits to a "limited" risk provider (becoming part of a physician group for example) then the provider is subject to the site visit requirement at the identified practice location. The SMA is able to rely on a site visit conducted by Medicare if:
 - 1. Medicare conducted a site visit at any of the practice locations listed on the Medicaid application,
 - 2. the site visit was conducted within the past 5 years, and
 - 3. the Medicare enrollment containing the practice address at which a visit was conducted is in an approved status.
- If a newly enrolling private practice physical therapist lists several practice locations under a single enrollment ID, the SMA has the discretion to determine the location at which the state (or state's contractor) will perform the site visit.
- If the private practice physical therapist's practice location is his or her home address and he/she exclusively performs services in patients' homes, nursing homes, a school, etc., the SMA is not required to conduct a site visit.
- If the physical therapist furnishes services in an institutional settings or a school the SMA is not required to conduct a site visit.

SMAs may apply these site visit policies to other individual Medicaid-only provider types in the "moderate" and "high" risk screening categories (i.e. personal care attendants, etc.), provided that the state documents these policies.

E. Activities that Constitute a Site Visit

1. Background

Per § 455.432(a), a site visit is designed to verify that the information submitted to the SMA is accurate and to determine compliance with federal and state enrollment requirements. Within this broad framework, the SMA has discretion to determine how it conducts site visits.

SMAs may face geographical challenges in conducting site visits due to terrain or distance. In these instances, CMS permits SMAs to conduct virtual site visits (i.e. Skype, FaceTime, etc.) for providers located in remote areas, provided that the method uses synchronous video conferencing technology. Pictures, for example, would not meet this criterion and would not be permissible.

1.5.5.4 Fingerprinting/Criminal Background Checks

A. General

1. Background

Under § 455.434, the SMA:

- As a condition of enrollment, must require providers to consent to criminal background checks (including fingerprinting) when required to do so under state law or by the applicable level of screening. (§ 455.434(a))
- Must establish categorical risk levels for providers and provider categories who pose an increased financial risk of fraud, waste or abuse to the State Medicaid Program. (§ 455.434(b))
- Upon the SMA determining that a provider, or a person with a 5 percent or more direct or indirect ownership interest in the provider, meets the SMA's criteria for criminal background checks as a "high" risk to the State Medicaid Program, the SMA will require that each such provider or person submit fingerprints. (§ 455.434(b)(1))
- The SMA must require a provider, or any person with a 5 percent or more direct or indirect ownership interest in the provider, to submit a set of fingerprints, in a form

and manner to be determined by the SMA, within 30 days upon request from CMS or the SMA. (§ 455.434(b)(2))

B. Collection of Fingerprints and Performance of Criminal Background Checks

1. Providers Subject to the Requirement

Please refer to Section 1.3.D "Risk Levels for Provider Types Also Existing in Medicare."

a. Individual "High" Risk Providers

"High" risk individual providers are subject to the FCBC requirement.

For more information regarding the provider types that are "high" risk, refer to section 1.3.D "Risk Levels for Provider Types Also Existing in Medicare."

b. Owners of "High" Risk Provider Types

For more information regarding the provider types that are "high" risk, refer to section 1.3.D "Risk Levels for Provider Types Also Existing in Medicare."

Five percent or more owners of "high" risk providers are subject to the FCBC requirement.

The 5 percent ownership threshold applies to all forms of organizations, including partnerships.

Thus, if an individual has, for instance, a 12 percent general or limited partnership interest in an entity, he or she is subject to a FCBC check. Also, if the SMA permits non-profit entities to have owners and a particular non-profit organization has a 5 percent for greater owner, he or she is subject to the FCBC requirement. Please refer to Section 1.3.D "Risk Levels for Provider Types Also Existing in Medicare."

2. Fingerprints

The SMA may determine the form and manner for submission of fingerprints within the scope of applicable laws and policies.

a. Cost Responsibility

Application fees are intended to cover the costs of a state's Medicaid provider screening program, including the cost to conduct FCBCs on "high" risk providers. However, the SMA may — and subject to the discussion in subsection 1.5.5.4.B.2.a "Cost Responsibility" below -- require "high" risk providers to pay the costs associated with collecting fingerprints.

3. Failure to Submit Fingerprints upon Request

If the provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit a set of fingerprints as prescribed by the SMA within 30 days of a CMS or SMA request, the SMA must terminate or deny enrollment unless the SMA determines that termination or denial is not in the Medicaid Program's best interests and documents that determination in writing. (See § 455.416(e)) This documentation must happen upon the state's determination to allow the provider to remain enrolled. "Upon" is defined here as within 60 days of the provider's noncompliance and the SMA's decision to retain the provider.

4. Owners/Providers Appearing on Multiple Enrollments

If the provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider has submitted a set of fingerprints to the SMA within the past 5 years (as an owner on a separate newly enrolling provider) the SMA is not required to request a new set of fingerprints. The SMA may rely on the results from the previous fingerprint submission.

1.6 Claims Processing

A. Denial of Claims

Under § 455.440, the SMA must deny claims for items or services that are ordered or referred that do not contain an NPI for the physician or other professional who ordered or referred such items or services.

1. Validating claims

When the NPI of an ORP appears on a claim, the SMA must validate that NPI and deny the claim if the NPI is not for an enrolled provider. The state should allow such a claim to pay only in the event that services were ordered or referred by a professional within a provider type not eligible to enroll under the State plan.

The SMA may provide access to enrollment information to rendering providers so that the latter can confirm that ordering or referring physicians or other professionals are Medicaid-enrolled. This information facilitates a rendering provider in accepting only those referrals made by providers enrolled in the reimbursing State's Medicaid Plan (i.e. referrals for potentially Medicaid-reimbursable services).

B. Enrolled Provider's Payment Eligibility for Retroactive Dates of Service

The practice of "backdating" enrollment involves approving an enrollment with a retroactive billing date. This practice allows a provider, once enrolled, to submit claims for services dated

prior to the date upon which the SMA approved the enrollment. As discussed earlier, provider screening enables states to identify ineligible parties before they are able to enroll and start billing. Components of provider screening include database and licensure checks, and may also include site visits and FCBCs. To the extent a SMA approves the enrollment of a new provider and permits the provider to bill for services dated prior to applicable screening(s), this practice creates risk. For example, if a newly enrolling provider is subject to a site visit, and the SMA completes a site visit for the provider but nonetheless permits the provider to bill for services dated prior to the date on which the site visit occurred, there is risk the provider was not present at the site on the date of service for which the provider is subsequently approved to bill.

It is incumbent upon the SMA to mitigate risk of improper payments as it determines a provider's eligibility for enrollment, including the date upon which a provider is deemed eligible to service Medicaid beneficiaries. The SMA should have a process to determine whether and when it is appropriate to approve an enrollment with a retroactive billing date, as doing so represents the SMA's determination of prior compliance. This process should be designed to mitigate risk.

Factors the SMA <u>must</u> take into consideration when approving a retrospective billing date include, but may not be limited to:

• Survey or certification requirements that supersede a state's ability to determine prior compliance

Factors the SMA might take into consideration when approving a retrospective billing date may include, but are not limited to:

- Emergency access
- Pre-authorization
- Whether a provider is enrolled in Medicare or another state's Medicaid Program

CMS recommends documenting the basis for establishing an enrollment with a retroactive billing eligibility date. Medicaid payment issued to a provider prior to the SMA's screening and enrollment of the provider is an improper payment, unless an exception applies as described under Section 1.5.1.

C. ORP Requirement: Institutional Claims

This guidance covers situations when reimbursement of institutional claims is contingent upon the order that serves as the basis for and upon which a claim is submitted.

Services provided following a beneficiary's admission to the hospital (or other institutional setting) are based upon orders which may be written by a number of physicians or other

authorized professionals. While it is required under § 455.410(b) for each individual ORP to be enrolled as a participating individual provider in Medicaid, it may not be feasible for the NPI of each individual ORP who ordered any item(s) or service(s) to be included on an institutional claim. It is therefore acceptable for the NPI of the individual provider who wrote the order of admission to appear on the claim in lieu of the NPI of each ORP who wrote an order during the beneficiary's stay. To the extent a physician or other authorized professional wrote the order of admission, that individual's NPI must appear on the associated claim; no additional NPI would need to be added to the claim to satisfy the requirement at § 455.440.

For example, if a Medicaid beneficiary is admitted to a hospital, the order to admit the beneficiary must have been written by a physician or other authorized professional. Under 45 CFR Part 162 Subpart D, electronically submitted institutional claims must list the NPI of the attending provider; to the extent the attending provider also wrote the order to admit the patient, no additional NPI would be required on the associated claim.

1.7 Documentation/Evidence of Completion

A. General Requirements – Documentation

1. Documentation Requirements That Apply When Provider Screening is Performed Manually

The SMA must be able to produce documentation to support having met each of the provider screening and enrollment requirements under 455 Subpart E.

When a screening activity is not captured in a form that serves to document that activity (for example, a SMA may capture a site visit in a site visit form or report, whereas a database check may not yield a piece of supporting documentation), the SMA should include a statement to confirm the screening activity was completed, using the following criteria:

- Statements must be stored so they can be produced on request: they can be stored electronically, but they are not required to be stored electronically.
- A statement should explicitly describe what requirement was completed and the
 date of completion. For example, "all databases checked" is not an acceptable
 statement of completion. "All databases checked 12/1/2014," is likewise not
 acceptable. "Checked the SSA DMF 12/1/2014" is acceptable to document that the
 SMA screened a provider against the Social Security Administration Death Master
 File. Each screening activity should be captured independently.

When a screening activity yields hard copy documentation, such as a site visit summary or copy of a provider's license, the documentation must be stored so that it can be produced upon request.

2. Documentation Requirements That Apply When Provider Screening is Performed by a System

The SMA must be able to produce documentation to support having met each of the provider screening and enrollment requirements under 455 Subpart E.

When a screening is performed by a system, the system must indicate the screening was performed. The SMA has discretion regarding the format of output showing screening was performed, however the log or output must indicate each required screening activity, a pass or fail result for that activity, and the date on which the screening was completed.

3. Documenting Reliance on Medicare's Screening

In order to rely on Medicare screening, the SMA is required to check Medicare's enrollment record (PECOS or the PECOS extract files). It is not necessary or recommended for a SMA to print or otherwise capture a screenshot of PECOS as documentation to support that the SMA checked PECOS. We recommend, but do not require, the SMA to document that it checked PECOS and the date.

a. Requesting Medicare Documentation from a Provider or a Medicare Administrative Contractor (MAC)

It is not acceptable for a SMA to require a provider or a MAC to produce evidence of their successful screening or enrollment in the Medicare Program. It is incumbent upon the SMA to directly check Medicare's enrollment record through its access to PECOS. This includes information concerning successful enrollment or revalidation, provider attributes (including, but not limited to, provider type), and elements of screening such as proof of FCBC completion or payment of an application fee. For example, a letter sent by the Medicare Administrative Contractor (MAC) to a Medicare provider to confirm successful Medicare enrollment (a MAC "welcome letter") does not provide supporting evidence that a SMA checked PECOS as required.

b. Relying upon Medicare "Certification" In Lieu of Verifying a Provider is Medicare-Enrolled

See Section 1.1.2.C. for a discussion of Medicare certification. Medicare certification, including a Medicare certification letter, is not equivalent to Medicare enrollment. The SMA cannot rely on Medicare certification as evidence a provider is, or will be, enrolled in Medicare. The SMA may rely on Medicare screening or enrollment only to the extent a provider is Medicare-enrolled in an approved status. The Medicare enrollment record reflects Medicare status, including "approved" status, for any Medicare provider.

B. Requirements Regarding Documenting FCBCs

The SMA must document the date that the FCBC was completed. However, documenting completion of the FCBC has specific considerations related to the sensitivity of criminal history information and the requirements to maintain the privacy and security of criminal history data. State Medicaid agencies must follow state and federal laws and regulations, including, if applicable, the policies and procedures set forth by the FBI when a state conducts a national criminal background check via the FBI. A SMA shall not store criminal history data in an enrollment record, regardless of whether the enrollment record is housed electronically or as a paper file.

1.8 Applications

A. Form and Manner

The SMA has the discretion to establish the form and manner of its application process.

B. Electronic Signatures

Electronic signatures of enrollment applications are permitted to the extent authorized under state law.

1.8.1 Application Fees

A. Background

1. General Requirement

Section 1866(j)(2)(C) of the Act requires the imposition of an application fee on each institutional provider "with respect to which screening is conducted," whenever the required screening (whether upon initial enrollment, reactivation, *revalidation* or reenrollment) occurs.

States must collect the applicable application fee prior to executing a provider agreement from a prospective or reenrolling provider other than the following:

- Individual physicians, non-physician practitioners, or other non-institutional providers.
- Providers that are enrolled in Medicare or in another State's Medicaid Plan. (§ 455.460(a)(2)(i))
- Providers that have paid the applicable application fee to CMS (i.e., a Medicare contractor) or to another state. (§ 455.460(a)(2)(ii))

Additionally, simple changes to the provider enrollment information, that is, new phone numbers, new bank account information, new billing address, change in the name of the provider or other such updates are not subject to the fee. The fee applies to newly-enrolling providers, revalidating providers, the addition of new practice locations, and the addition of a new owner(s).

B. Fee Amount

The application fee amount is the same as the application fee that applies to Medicare enrollment. The application fee increases each calendar year based on the consumer price index for all urban consumers.

CMS notifies stakeholders of the fee that applies to a subsequent calendar year, by:

- Issuing a "Notice" action in the Federal Register,
- Issuing guidance to the State Medicaid Directors,
- Issuing CMS provider and supplier listserv messages,
- Making announcements at CMS Open Door Forums, and
- Placing information on the CMS Provider/Supplier Enrollment Web page (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/MedicareApplicationFee.html)

C. Application Fee: Purpose and Use

Any application fees collected by States must be used to offset the cost of conducting the required screening. State expenditures incurred for the administration of the program can be reimbursed at 50 percent FFP. This includes both the costs of the screening that exceed the fees collected and the additional costs of administering the State's program. To report State administrative costs and to request reimbursement, States must report expenditures and revenues on the Medicaid Budget and Expenditure System, form CMS-64. Additionally, if revenue from application fees exceeds the State's cost of conducting the required screening, States are required by 42 CFR 455.460 to return to CMS the portion of the application fees which exceed State administrative costs. For example, if a State's costs to conduct the screening required by 42 CFR 455 subpart E are \$100 million and revenue from application fees equals \$60 million, States may request FFP at 50 percent for the remaining \$40 million for the administration of the provider enrollment and screening initiative. Alternatively, if the cost to implement these requirements is \$60 million and the revenue from application fees is \$100

million, States are required to return to CMS the \$40 million in application fees that exceed the costs of the screening.

D. Collection

An institutional provider should pay one fee, at an enrollment level, regardless of how many physicians reassign their benefits to that institution. An institutional provider pays a fee on a per application basis. For example, if a provider submits a single application containing multiple practice locations, the provider pays a single fee.

- 1. Affected Providers
- a. Institutional Providers

Any providers who are considered institutional in Medicare are also considered institutional in Medicaid. Medicare does not use a broader definition of institutional than Medicaid. Medicare defines the following provider types as "institutional" for purposes of the application fee:

- Ambulatory surgical centers
- Ambulance service suppliers
- Community mental health centers (CMHCs)
- Comprehensive outpatient rehabilitation facilities (CORFs)
- Competitive Acquisition Program/Part B Vendors
- DMEPOS suppliers
- End-stage renal disease facilities
- Federally qualified health centers
- Health programs operated by an Indian health program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian health service pursuant to Title V of the Indian Health Care Improvement Act
- Histocompatibility laboratories

- Home health agencies (including HHAs that must submit an initial enrollment application pursuant to § 424.550(b)(1))
- Hospices
- Hospitals
- Independent clinical laboratories
- Independent diagnostic testing facilities
- Mammography screening centers
- Mass immunization roster billers
- Nursing Facility (other)
- Outpatient physical therapy/outpatient speech pathology providers enrolling via the Form CMS-855A
- Organ procurement organization (OPO)
- Pharmacies that are newly enrolling or revalidating via the Form CMS-855B application
- Portable x-ray suppliers (PXRS)
- Radiation therapy centers
- Religious non-medical health care institutions (RNHCI)
- Rural health clinics
- Skilled nursing facilities

With respect to Medicaid-only provider types, the applicability of the fee depends on whether the provider type is "institutional." A SMA should use its knowledge of Medicaid-only provider types to make this determination. The criteria in Section "C. Concept of Institutional" may assist the SMA to determine whether a provider is institutional. However, these criteria are not determinative, as there are other provider types considered to be institutional and to which the application fee applies. For example, in the preamble to the February 2, 2011 final rule, in addition to the providers and suppliers in the bulleted listed above, for purposes of Medicaid

and CHIP, we stated that a State Medicaid Plan may impose the application fee on any institutional entity that bills the State Medicaid program or CHIP on a fee-for-service basis, such as, but not limited to: personal care agencies, non-emergency transportation providers, and residential treatment centers, in accordance with the approved Medicaid or CHIP State plan.

Once a state has determined that a provider/supplier is institutional, they should apply that determination to all providers/suppliers of the same type.

2. Enrollment as Different Provider Types

Entities that are enrolled as multiple provider types must be screened separately for each enrollment.

If an entity is enrolling as two separate institutional provider types, two fees will apply, unless the SMA is able to rely on Medicare or another state's Medicaid agency's collection of the application fee as described in the section below.

E. When Not to Collect: Exemptions and Waivers

1. Non-Institutional Providers

Non-institutional providers such as individual practitioners and group practices are exempt from the application fee.

There is confusion about the statute regarding whether application fees apply to individual providers because there is an error in the online text for the Social Security Act at §1866(j)(2)(C)(i) reflecting language for an individual app fee. However, the provision for an application fee for individual providers was removed in the reconciliation process for the Affordable Care Act (ACA), by section 10603(a). The mistake online is not reflected in the correct "Yellow Book" of the ACA. No individual fee is authorized by the statute or CMS regulations.

2. Relying on Medicare to Collect the Application Fee

Under § 455.460, the SMA must not collect an application fee from a provider that has paid an application fee to Medicare or another state's Medicaid Program.

Additionally, under § 455.460, the SMA must not collect an application fee from a provider that is enrolled in Medicare or another state's Medicaid Program.

To ensure that the requirements of § 455.460(a) are met and that there is the least duplication of fee payment collections by Medicaid and Medicare, the SMA shall follow the guidance in this subsection.

a. Medicare/Medicaid Dually Enrolled Providers:

The SMA should follow the guidance in this section to determine whether it shall rely on Medicare to collect the application fee instead of the SMA.

This guidance applies when an institutional Medicaid provider submits an enrollment application to the SMA for:

- New enrollment
- Revalidation
- An update to the enrollment that adds a practice location
- An update to the enrollment that adds an ownership interest

Similar to the process the SMA uses to determine whether it may rely on Medicare's screening activity, if the provider is in an "approved" Medicare enrollment status, the SMA should compare the Medicaid enrollment application to the Medicare enrollment information using the data elements shown in Table 3 below.

If any of the data elements noted in the Table 3 below do not match, the SMA should charge an application (see note) fee to process the application and the SMA should proceed to conduct required screening activities based on those data elements that differ.

If all the required elements are a positive match, the SMA should not charge an application fee, regardless of when or whether the provider last paid any application fee to Medicare. The SMA should not charge a fee even when there is a difference between the Medicaid and Medicare risk levels that requires the SMA to conduct additional screening activities, as described under Section 1.5.3.A.1 "Instructions for relying on provider screening conducted by Medicare (§ 455.410) or conducting additional screening when required."

Table 3

	Medicaid Risk	Name	TIN	Practice	5 % or
	Category			Location(s)	more
					owners
Institutional	"Limited"	Χ	Χ		Χ
Organizational	"Moderate"	Χ	Χ	Χ	Х
Provider	"High"	Χ	Χ	Χ	Х

Example 1:

An Ambulatory Surgical Center submits a new enrollment application to the SMA. The provider's Medicaid risk category is "limited." The provider is dually enrolled in Medicare, with the same name, TIN, and 5 percent or more owners as what is reflected on the provider's Medicaid application. The SMA processes the application without requiring a fee. The SMA is able to rely on Medicare's screening meet its own screening requirements.

A HHA submits a new enrollment application to the SMA. The provider's Medicaid risk category is "high." The provider is dually enrolled in Medicare in a "moderate" risk category with the same name, TIN, practice location, and 5 percent or more owners as what is reflected on the provider's Medicaid application. The SMA processes the application without requiring a fee. Based on verifying the matching provider's "approved" Medicare status, the SMA is able to rely on Medicare's screening activities up to and including the risk screening activities corresponding to the "moderate" risk category. The SMA must verify Medicare conducted a FCBC or conduct a FCBC itself.

b. Verification of Medicare Fee Payment

If a SMA may rely on Medicare's screening to fully satisfy its own screening requirements, and Medicare's enrollment record does not reflect the provider paid an application fee, the SMA must not collect a fee.

c. Refunds

If an institutional provider is enrolled in Medicaid and has paid an application fee, and the provider subsequently enrolls in Medicare, the provider must pay a duplicate application fee to Medicare. Unlike in Medicaid, in Medicare there is no regulatory provision that allows Medicare to not collect a fee, outside of a hardship waiver; thus, within 5 years of the provider's Medicaid application approval date, the provider may request a refund from the SMA. The SMA may not ask the provider to supply proof that the fee was paid to Medicare, because the information is available in PECOS. The SMA, in this situation, refunds the application fee to the provider, upon the provider's request.

3. Provider Is Enrolled in Other Medicaid Plan

Since there is no national enrollment database for Medicaid providers, the SMA should ask the provider whether it is enrolling or has enrolled in another State's Medicaid Plan. If the provider responds in the affirmative, the SMA should contact the other SMA to confirm this information. States are encouraged to work together to determine which SMA should collect the application fee (and conduct the required screening) if the provider is enrolling in multiple states. Similarly, if a state operates separate Medicaid Programs, the programs should coordinate to ensure that there is no duplication of fee payments if a provider is enrolling in both programs.

- 4. Individual Hardship Exceptions
- a. Relevant Statutory and Regulatory Provisions
 - Section 1866(j)(2)(C)(ii) of the Act permits the Secretary (i.e., CMS) to grant, on a case-by-case basis, exceptions to the application fee for institutional providers and suppliers enrolled in the Medicaid Program if the Secretary determines that imposition of the fee would result in a hardship.
 - Under § 424.514(f), a hardship exception request must contain a letter that
 describes the hardship and why the hardship justifies an exception to the application
 fee requirement.
 - Under § 424.514(h), CMS has 60 days in which to approve or disapprove a hardship exception request.
- b. Hardship Exception Process
- i. SMA Submission Process

The application review process follows:

- The SMA requires a letter from the provider describing the hardship and why the hardship justifies an exception to the application fee requirement. The provider submits the letter and supporting documentation to the SMA in accordance with the state's policy for submission.
 - The supporting documentation may include but is not limited to historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.
- The state evaluates the documentation and continues the process <u>only if the SMA</u> agrees the provider has demonstrated a hardship.
- A SMA may deny a provider's hardship exception request or may recommend approval by CMS. Only CMS may approve a request.
- If the state recommends approval of a request, it forwards the following to CMS by email (MedicaidProviderEnrollment@cms.hhs.gov):
 - Provider's request package
 - The provider's NPI and address

ii. CMS Review Process

- CMS will review complete hardship exception packages. If a package is not complete, CMS will request the state to develop for completeness.
- If the provider has already paid an application fee to Medicare, *CMS* will notify the state that the provider is not subject to a fee, and CMS will not review the package for a decision. Otherwise, CMS will review the package submitted for a decision.
- If CMS determines additional documentation is required from the provider to demonstrate hardship, CMS will send a letter to the SMA to notify the state that more information is required. The state has 30 days to respond with the additional supporting documentation. If CMS does not receive documentation in the required time frame, CMS will take no further action.
- Within 60 days of the state's submission of the hardship exception recommendation, CMS will reply by email to the individual who submitted the recommendation or to the general mailbox that the state uses to submit the recommendations. In the email, CMS will supply a decision letter.
- The state communicates with the provider and the area that is responsible for collection of the fee. CMS does NOT communicate directly with the provider. CMS only communicates with the state.
- In the case of denial, the state may ask for reconsideration. In this situation, the state should, but is not required to, supply additional documentation to support their position that the exception should be granted.

5. Access Waiver

In addition to the case-by-case hardship exceptions discussed above, § 1866(j)(2)(C)(ii) also permits CMS to waive the application fee for certain non-Medicare enrolled Medicaid providers (such as those within a certain provider type and/or geographic area) when the state demonstrates that the imposition of the fee on those providers would impede beneficiary access to care. To request a waiver on this basis, the State Medicaid Plan must submit a letter requesting CMS' approval for such a waiver. The letter from the State Medicaid Plan must establish the supporting basis for a waiver based on access to care considerations. CMS will approve or deny the State Medicaid Plan's request and reply by letter to the State Medicaid Plan.

1.9 Denials

This section covers the SMA's denial of new enrollment applications.

A. Mandatory Denials

Under § 455.416, the SMA must deny the provider's enrollment application in the following circumstances:

- Any person with a 5 percent or more direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with Medicare and Medicaid in the last 10 years, unless the SMA determines that denial is not in the Medicaid Program's best interests and documents that determination in writing. (§ 455.416(b))
- The provider is terminated under Medicare or under the Medicaid Plan of any other state. (§ 455.416(c)) This provision is limited to "terminations" as defined in § 455.101. In contrast to the other circumstances in which denial is required, the SMA does not have the authority to determine that in this circumstance denial is not in the Medicaid Program's best interests.
- The provider, or a person with an ownership or control interest or who is an agent or managing employee of the provider, fails to submit timely or accurate information, unless the SMA determines that denial is not in the Medicaid Program's best interests and documents that determination in writing. (§ 455.416(d))
- The provider, or any person with a 5 percent or greater direct or indirect ownership
 interest in the provider, fails to submit a set of fingerprints as prescribed by the SMA
 within 30 days of a CMS or SMA request, unless the SMA determines that denial is
 not in the Medicaid Program's best interests and documents that determination in
 writing. (§ 455.416(e))
- The provider fails to permit access to provider locations for any site visits under § 455.432, unless the SMA determines that denial is not in the Medicaid Program's best interests and documents that determination in writing. (§ 455.416(f))

B. Discretionary Denials

Under § 455.416(g), the SMA may deny the provider's enrollment application if it:

 Determines that the provider has falsified any information provided on the application; or • Cannot verify the identity of any provider applicant.

The SMA may also deny an application if the application does not meet applicable state requirements (e.g., requirements in state regulations).

Under § 431.51(c)(2), the State Medicaid Plan has the authority to set reasonable standards relating to the qualifications of providers.

1.10 Terminations

1.10.1 Purpose

This section covers the State Medicaid Agencies' terminations of existing provider agreements.

A. Definitions

The definitions below are only provided to assist the SMAs in determining how CMS defines certain terms; this list is nonbinding on SMAs. For the purpose of termination reporting, CMS defines the following terms as indicated below:

Enrollment Bar Expiration Date means the date on which the SMA's termination period ends and a provider is eligible to apply to reenroll in the State Medicaid Agency's plan. This does not mean they are guaranteed reinstatement of billing privileges. In order to have billing privileges reinstated, a provider must still meet enrollment requirements.

Enrollment Deactivation/ Deactivate means that the provider's billing privileges were stopped, but can be restored upon the submission of updated information.

Enrollment Suspension means the same as enrollment deactivation/ deactivate.

Exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid, and/or all other Federal health care programs until the individual or entity is reinstated by the HHS OIG. Exclusion from participation in a federal health care program (e.g., Medicare and Medicaid) is a penalty imposed on a provider by the HHS OIG under §1128 or §1128A of the Social Security Act. Individuals and entities may be excluded by the HHS OIG for misconduct ranging from fraud convictions, to patient abuse, to defaulting on health education loans. States may also exclude providers from their Medicaid Programs under state law or pursuant to 42 CFR. § Part 1002.

For Cause Termination means a termination, as defined below, by a SMA of the provider's billing privileges, of which all applicable appeal rights have been exhausted or the time for appeal has expired. For Cause terminations are terminations related to fraud, integrity, or quality issues which run counter to the overall success of the Medicaid Program. For the purpose of CMS review, "for cause" reasons for termination closely mirror the regulatory authorities for Medicare revocations found in 42 CFR § 424.535.

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 operation of an institution, organization, or agency.

Pend License means that the provider's license has been suspended. See "Suspension/ Suspended".

Preclusion/ Precluded means banned or barred from enrolling or reenrolling in Medicaid, or any other federal health care program. CMS views preclusion as an exclusion. See "Exclusion."

Revocation/ Revoked means the provider's Medicare billing privileges and any corresponding provider agreement have been adversely terminated. Revocation reasons are located under 42 CFR § 424.535.

Suspension/Suspended:

- (a) **License Suspension (Temporary or Indefinite)** means the provider's ability to render services has been stopped.
- (b) Partial/ Probationary License Suspension means that the provider's license has been restricted until certain requirements are met by the provider and/or the provider is restricted from performing certain services, performing certain acts, or required to undergo to certain screenings. Partial suspension does not mean the provider's ability to render services has been stopped completely.
- (c) **Payment Suspension** means the withholding of Medicare or Medicaid payment from a provider for an approved payment amount, before a determination of the amount of the overpayment exists, or until resolution of an investigation of a credible allegation of fraud.
- (d) Stay of License Suspension means a postponement of administrative or judicial action or that the order resulting from action has been set aside, allowing the provider to render services if the provider complies with certain terms of an agreement.

Termination means, under 42 CFR § 455.101,

- (1) For a—
- (i) Medicaid provider, a State Medicaid Program has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired; and
- (ii) Medicare provider, supplier or eligible professional, the Medicare Program has revoked the provider or supplier's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired.
- (2)(i) In all three programs, there is no expectation on the part of the provider or supplier or the state or Medicare Program that the revocation is temporary.
- (ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated.
- (3) The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to—(i) fraud; (ii) integrity; or (iii) quality.

1.10.2 For Cause Terminations: Mandatory vs. Discretionary Terminations

Terminations are inclusive of both mandatory and discretionary terminations. For the purpose of reporting requirements as defined under section 1.10.4 of this compendium, "for cause" mandatory and discretionary terminations are identified as follows:

A. Mandatory Termination

Each mandatory termination authority under 42 CFR § 455.416 or identified as a Medicare "for cause" revocation reason under 42 CFR § 424.535 for which Medicaid is required to terminate is deemed a "for cause termination" as defined under section 1.10.1.A of this compendium.

Pursuant to 42 CFR § 455.101, the requirement for denial or termination based on the action of Medicare or another SMA applies where providers were terminated or had their billing privileges revoked by another program for actions including but not limited to reasons related to fraud, integrity, or quality.

Each mandatory termination reported under § 455.416(c) shall include only terminations for which the provider has:

(a) Exhausted appeal rights, or

(b) The timeline for appeal has expired. See also section 1.10.3.B of this compendium and § 455.101.

It is mandatory for all SMAs to terminate a provider in all of the following "for cause" circumstances:

- (a) Criminal Conviction. The provider or any person with a 5 percent or more direct or indirect ownership interest in the provider was within the preceding 10 years convicted (as defined in 42 CFR § 1001.2) of a Federal or State criminal offense related to that person's involvement with Medicare, Medicaid or CHIP. This requirement applies unless the SMA determines that termination is not in the Medicaid Program's best interests and documents that determination in writing. 42 CFR § 455.416(b).
- (b) Failure to Comply with Screening Requirements. Where any person with a 5 percent or more direct or indirect ownership interest in the provider did not submit timely and accurate information and cooperate with any screening methods required under 42 CFR Part 455 Subpart E. 42 CFR § 455.416(a).
- (c) Failure to Submit Fingerprints. Where the provider, or any person with a 5 percent or more direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the SMA within 30 days of a CMS or SMA request, unless the SMA determines that the termination or denial of enrollment is not in the best interests of the Medicaid program and the SMA documents that determination in writing. 42 CFR § 455.416(e).
- (d) Failure to Submit Timely and Accurate Information. The provider or a person with an ownership control interest, an agent, or managing employee of the provider failed to submit timely and accurate information, unless the SMA determines that termination is not in the Medicaid Program's best interests and documents that determination in writing. 42 CFR § 455.416(d).
- (e) **Onsite Review.** The provider fails to permit access to provider locations for any site visit, unless the SMA determines the termination is not in the best interests of the Medicaid program. 42 CFR § 455.416(f).
- (f) Terminated or Revoked for Cause under Separate Medicaid or Medicare Enrollment. Where the provider's enrollment has been terminated or revoked "for cause" by Medicare or another state's Medicaid program and such termination has been published in the Data Exchange System

(DEX), the SMA shall terminate the provider's enrollment in its program. 42 CFR § 455.416(c), § 455.101.

B. Discretionary Termination

Discretionary terminations may be "for cause" terminations as defined under section 1.10.1.A of this compendium. Please note that SMAs must ensure all terminations are in line with "Free Choice of Provider" provisions. For more information, please reference §1902(a)(23); 42 CFR § 431.51.

1. For Cause Discretionary Termination Reasons

The SMA may terminate the provider's enrollment for the following discretionary "for cause" termination reasons:

- (a) Abuse of Billing Privileges. The provider submits a claim or claims for services that could not have been furnished to a specific individual on the date of service including when the beneficiary is deceased, where the directive physician or the beneficiary is not in the state when the services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.
- (b) **Billing with Suspended License.** Billing for services furnished while the provider's license is in a state of suspension.
- (c) False or Misleading Information. The provider certified as "true" false or misleading information on their enrollment application to be enrolled or maintain enrollment in the State Medicaid program. Please note that CMS considers this authority mandatory under the Medicare program. 42 CFR § 455.416(g)(1).
- (d) Improper Prescribing Practices. The SMA determines that a provider has a pattern of practice of prescribing drugs that is abusive or represents a threat to the health and safety of Medicaid beneficiaries or the pattern or practice of prescribing fails to meet Medicaid requirements.
- (e) **Inability to Verify**. The SMA cannot verify the identity of any provider applicant. 42 CFR § 455.416(g)(2).

- (f) **Misuse of Billing Number**. The provider knowingly sells to or allows another individual or entity to use its billing number, other than a valid reassignment of benefits.
- (g) **Noncompliance.** The provider is determined to not be in compliance with enrollment requirements established by the SMA. This does not include license expiration.
- (h) Noncompliance with Licensure Standards. When the provider has been subject to an adverse licensure action resulting in the loss of license. This does not include license expiration.
- (i) **Onsite Review**. The provider failed onsite review due to one of the following circumstances:
 - (i) No longer operational to furnish Medicaid covered items or services
 - (ii) Otherwise fails to satisfy any Medicaid enrollment requirement
- (j) Other. Any other reason that poses a threat of fraud, waste, or abuse to the Medicaid program.
- (k) **Prescribing Authority**. The provider's Drug Enforcement Administration Certificate of Registration is suspended or revoked or the applicable licensing or administrative body for any state in which the provider practices suspends or revokes the provider's ability to prescribe drugs.
- (I) **Provider Conduct.** The provider or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider is:
 - (i) Excluded from the Medicare, Medicaid, or any other health care program as defined in 42 CFR § 1001.2.
 - (ii) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with FASA implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.
 - (iii) Any other state or federal exclusion.

Please note that an individual or entity found on the

LEIE/MED lists is ineligible to receive payments from Medicaid, Medicare, or any other federal healthcare program (see SMDL #19-001, Jan 16, 2009 for additional background). Accordingly, payments made for items or services furnished by an excluded provider are not eligible for FFP.

1.10.3 Implementation of Terminations

A. Data Source for Medicare "For Cause" Revocations, Medicaid "For Cause" Terminations and HHS OIG Exclusions

Medicare revocations occur when a provider's Medicare billing privileges and any corresponding provider agreement have been adversely terminated from the Medicare program. Medicare revokes providers both on a "for cause" or a "not for cause" basis. Accordingly, PECOS is not an acceptable source for a state to identify "for cause" revocations.

Medicaid terminations occur when a provider's Medicaid billing privileges, of which all applicable appeal rights have been exhausted or the time for appeal has expired, and any corresponding provider agreement have been adversely terminated from a State Medicaid program.

Exclusion from participation in a federal health care program (e.g., Medicare and Medicaid) is a penalty imposed on a provider by the HHS OIG under §1128 or §1128A of the Social Security Act. HHS OIG excludes individuals and entities for misconduct ranging from fraud convictions, to patient abuse, to defaulting on health education loans. An HHS OIG exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid, and/or all other Federal health care programs until the individual or entity is reinstated by the HHS OIG.

In order to access Medicare revocations, State Medicaid Agency terminations, and HHS OIG exclusions which would trigger a state's obligation to terminate pursuant to § 455.416(c) and 455.101, CMS established secure access for states to the Data Exchange System (DEX). *DEX must be searched as part of the state's screening process.* Please note that all adverse actions in DEX are "for cause" and have exhausted their first level appeal rights.

B. Appeals Exhaustion

Consistent with the definition of "termination" in § 455.101 (also see under section 1.10.1.A of this compendium), the SMA shall not terminate the provider under § 455.416(c) unless the provider has exhausted appeal rights with respect to the other program's termination or the

timeframe for such appeal has expired. CMS does not share "for cause" revocations or HHS OIG sanctions with SMAs in DEX until their time for initial appeal has lapsed; therefore, SMAs must take action on any revoked or excluded provider found in DEX.

Additionally, State Medicaid terminations are not reported to CMS until all applicable appeal rights have been exhausted at the state level, therefore, states are also required to take action on any terminated provider found in DEX.

C. Appeals Related to Another SMA's Termination

Consistent with § 455.416(b), SMAs shall take immediate termination action on any and all providers that another SMA terminated "for cause." The SMA shall terminate immediately and may afford appeal rights to the provider after the immediate termination action. The terminated provider shall not be eligible for reimbursement for services furnished during any potential appeal process.

D. Effective Date of Termination

For purposes of complying with § 455.416(c), a SMA shall use the date CMS published the termination in DEX as the effective date of another state's termination. *The date CMS published the termination is found in Column S of the adverse actions report. This date is also found on the provider's card in DEX.*

For felonies or exclusions, a SMA shall use the effective date of the exclusion because when HHS OIG excludes a provider, Federal health care programs (including Medicaid and CHIP programs) are generally prohibited from paying for any items or services furnished, ordered, or prescribed by excluded individuals or entities. (Section 1903(i)(2) of the Act; and 42 CFR section 1001.1901(b)) This effective date is found in Column I in the adverse actions report and is also found on the provider's adverse action's card in DEX.

1.10.4 Medicaid Termination Reporting

A. Duty to Report

The SMA shall report providers terminated on or after January 1, 2011. The SMA shall only report providers it has terminated "for cause" from its Medicaid Program and for which the appeal process is exhausted or the time for appeal has expired. These terminations shall be reported within 30 days of the date the termination becomes ripe for reporting. For more information on for cause terminations (mandatory vs. discretionary terminations) see section 1.10.2 of this compendium and for more information on appeals related to another SMAs termination see section 1.10.3.C. of this compendium.

B. Termination Reporting and CMS Review Process

1. Method

SMAs shall report terminations to CMS via DEX. These terminations may be reported one at a time or multiple terminations at one time by clicking the "Report Terminations" button in DEX.

To report a termination to CMS via DEX, click on the "Report Terminations" button and select "Report Single Termination." Then, select the provider's enrollment type (Individual, Organization or Individual Enrolled as an Organization) and enter the provider's name as well as the required numerical identifiers. Complete all required fields marked by a red asterisk and click continue. Lastly, enter the termination's details in the system and click "Report Termination" to report the termination to CMS.

To report multiple terminations at one time to CMS via DEX, click on the "Report Terminations" button and select "Report Multiple Terminations." Then, download the pre-formatted template by clicking on "Download Bulk Terminations Template" and complete it by adding the terminated providers' information in their respective columns. It is required to include:

- (a) Enrollment Type: Complete the template with "Individual," "Organization," or "Ind as Org." Ind as Org (Individual Enrolled as an Organization) is a group enrollment that has a SSN and a legal name. These enrollments are often sole proprietors.
- (b) Provider Specialty
- (c) NPI and/ or SSN for individual providers
- (d) NPI and/ or EIN for organizational providers
- (e) First and last name for individual providers as well as date of birth
- (f) Legal Business Name for organizational providers
- (g) First and last name in the Legal Business Name field as well as the provider's SSN for Individuals Enrolled as Organizations
- (h) Appeals Expiration: The SMA must confirm that all applicable appeal rights have been exhausted by entering "yes" or "no" in the template. CMS will not publish a termination in DEX if the provider's appeal rights have not been exhausted.
- (i) Termination Effective Date

- (j) Termination Reason: The state may enter more than one "for cause" termination reason by separating each reason with a coma.
- (k) Correspondence address, city, state, and zip code
- (I) Eligible to Reapply Date: The SMA must report the date the Medicaid termination period ends or indicate "indefinite" if the provider is not eligible to reapply for enrollment.

Although not required, the SMA may also include the terminated providers' state license type and number in the bulk termination template. Once the template is completed, upload it to DEX. In addition to the bulk termination template, the SMA shall also upload a .zip file containing the corresponding termination letters. Once the template and the .zip file containing the applicable termination letters have been uploaded to DEX, click continue to report the terminations to CMS.

2. CMS Termination Review Process

CMS reviews all terminations reported by SMAs and then publishes the terminations to all States in DEX within 30 days after a termination is reported by a SMA. These terminations then become searchable in DEX and downloadable via the adverse actions report.

If CMS needs additional information on a termination before publishing it, CMS will return the termination to the state. Returned terminations can be found in the SMA's "returned actions" tab in DEX and must be edited and resubmitted to CMS in order to be published.

C. Adverse Actions Report

The adverse actions report contains all providers revoked "for cause" by Medicare, terminated "for cause" by State Medicaid Agencies, and excluded by the HHS OIG. At least monthly, the SMA shall download and compare the adverse actions report to its population of actively enrolled providers to determine whether the SMA needs to terminate any provider enrolled in its program. The adverse actions report contains the following information:

- (a) Enrollment Type: Individual, Organization, Individual Enrolled as an Organization
- (b) Numerical Identifiers: NPI, SSN, and/or EIN
- (c) Provider Name: First and last names for individual providers or Legal Business Name for organizational providers

- (d) Appeals Period: This column confirms that the provider's appeals period has expired. This field is populated with "yes" for all terminations and with "N/A" for all revocations and all HHS OIG sanctions because these providers' time for initial appeal has expired.
- (e) Adverse Action Effective Date: Termination, revocation, or sanction effective date
- (f) Adverse Actions Reason: Description of the "for cause" reason for the adverse action
- (g) Correspondence address, city, state, and zip code
- (h) Enrollment Bar: This column indicates whether the provider is under an active enrollment bar as of the download date of the adverse actions report. When this field is populated with "no" the provider's enrollment bar has expired or the provider has been reinstated making them eligible to apply for enrollment.
- (i) Enrollment Bar Expiration Date: This field is populated with the date the provider's enrollment bar expires. On and after that date, the provider is eligible to submit an enrollment application. In some cases, terminations are indefinite and providers may not re-enroll.
- (j) Adverse Action Status
- (k) Terminating Program: For terminations, this field is populated with the state abbreviations of the SMA that reported the termination to CMS. For revocations, this field is populated with "Medicare." For exclusions, this field is populated with "HHS OIG."
- (I) CMS Published Date: This fields contains the date CMS published the adverse action to DEX.
- (m) Practice location address, city, state, and zip code
- (n) CMS Notes: This column contains additional information on the adverse actions including whether a provider has been reinstated or an adverse action has been overturned. SMAs shall review this information before taking termination action against a provider.
- (o) Medicare Enrollment State and Enrollment ID: The Medicare enrollment state and the Medicare enrollment ID is populated in these fields for all Medicare revocations.
- (p) Termination Letter: The termination letter links in the adverse actions report are inactive at this time but SMAs can search and download termination letters by searching the terminated provider in the DEX search bar and clicking on the letter icon located in the provider's termination card.

(q) Waiver Note, Waiver Effective Date, and Waiver End Date: Waiver information is populated in these fields for HHS OIG exclusions, if applicable.

D. Provider Matching

The adverse actions report contains all providers revoked "for cause" by Medicare, terminated "for cause" by State Medicaid Agencies and excluded by the HHS OIG. At least monthly, the SMA shall download and compare the adverse actions report to its population of actively enrolled providers to determine whether the SMA needs to terminate any enrolled provider in its program.

For organizational providers found on the adverse actions report, to determine if the provider is the same as a provider enrolled or newly enrolling in a SMA, the SMA shall match the EIN and legal business name.

For individual providers, to determine if the provider is the same as a provider enrolled or newly enrolling in a SMA, the SMA shall match the NPI or the last 4 digits of the SSN as well as the provider's first and last name. The SMA will use its discretion to determine a name match (John W. Smith vs. John William Smith, etc.).

For individuals enrolled as organizations, to determine if the entity is the same as an entity enrolled or newly enrolling in a SMA, the SMA shall match the NPI or the last 4 digits of the SSN as well as the legal name. The SMA will also use its discretion to determine a name match (Joe Smith vs. Joseph Smith).

Per 42 CFR §455.416(c) and 42 CFR §455.101:

- (a) If a 1) positive match is found, 2) the provider is actively enrolled in the SMA, and 3) the provider's enrollment bar has not expired, the SMA shall terminate the provider's enrollment. Once the termination's appeal's period has expired, the SMA shall then report the termination to CMS via DEX.
- (b) If a 1) positive match is found, 2) the provider is seeking enrollment in the SMA (i.e. initial enrollment, revalidation, or re-enrollment), and 3) the provider's enrollment bar has not expired, the SMA shall deny the provider's enrollment.

E. Reinstating a Terminated Provider and Rescinding a Termination

A SMA can reinstate a terminated provider and rescind a termination it reported to CMS. Reinstating a terminated provider modifies the expiration of the provider's enrollment bar. To reinstate a terminated provider in DEX, the SMA should search the provider in the search bar, click on the "edit termination" button in the termination card, edit the enrollment bar expiration date, and upload the reinstatement letter as supporting document.

A SMA may also rescind a termination it reported to CMS. Rescinding a termination is only appropriate if the termination is fully removed from the provider's record. For example, this may occur in cases where a higher court overturns a termination. Rescinding a termination removes the provider's enrollment bar thus changing the enrollment bar expiration date to the termination effective date. To rescind a terminated provider in DEX, the SMA should search the provider in the search bar, click on the "edit termination" button, scroll down to the bottom of the page, click on the rescind termination button and click continue.

F. Reenrollment after Termination

After the expiration of the enrollment bar, a provider wishing to again participate in the program must reapply and meet all applicable enrollment requirements. SMAs have the discretion to determine when and whether a terminated provider whose enrollment bar has expired is eligible to apply for reenrollment in their State Medicaid program.

1.10.5 Timely Action

A. Action Based on a Revocation, Termination or Sanction

A SMA is expected to take timely action based on Medicare "for cause" revocations, Medicaid "for cause" terminations, and HHS OIG Sanctions. Timely action is defined as within 60 calendar days from the date upon which CMS published the adverse actions in DEX. CMS does not notify a SMA of an adverse action in DEX until the provider's appeal rights are exhausted or the timeframe for such appeal has expired. A SMA shall also rescind any termination it effectuated within 30 days of the date CMS published a rescission of such termination in DEX.

B. Untimely Action Based on a Revocation, Termination or Sanction

A SMA that takes untimely termination action based on a Medicare "for cause" revocation, a Medicaid "for cause" termination or an HHS OIG Sanction may lose Federal Financial Participation (FFP) due to failure to comply with the federal regulation at § 455.416.

1.11 Appeals

A. General Requirement

Under § 455.422, the SMA must give providers that are denied or terminated under § 455.416 any appeal rights available under procedures established by state law or regulations.

B. Scope of Termination Appeals

The scope of appeals for the original terminating program (i.e., Medicare or Medicaid) should include a full appeal on the merits regarding the basis of the termination. The original terminating program's appeals process shall provide for review of the underlying basis for the termination, but no other state's appeals process shall provide for such review. When other states subsequently terminate the provider based upon that initial termination, the scope of any appeal of the subsequent termination shall be restricted to whether the provider was, in fact, terminated by the initiating program, and shall not provide for a review of the basis for the original action.

1.12 Moratoria

A. CMS-Imposed Moratoria

Under § 455.470(a):

- Prior to imposing moratoria under § 424.570, the Secretary (CMS) consults with any affected SMA regarding the imposition of temporary moratoria on enrolling new providers or provider types. (§ 455.470(a)(1))
- The SMA will impose temporary moratoria on enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid Program. (§ 455.470(a)(2))
- The SMA is not required to impose such a moratorium, if the SMA determines that imposing the moratorium would adversely affect beneficiaries' access to medical assistance. (§ 455.470(a)(3)(i))
 - If the SMA makes such a determination, the SMA must notify the Secretary in writing. (§ 455.470(a)(3)(ii)) CMS recommends that the SMA explain the bases of its concerns regarding beneficiary access to care.

B. State-Imposed Moratoria

Under § 455.470(b):

 The SMA may impose temporary moratoria on enrolling new providers or provider types that the SMA identifies as having a significant potential for fraud, waste, or abuse and that the Secretary has identified as being at high risk for fraud, waste, or abuse. (§ 455.470(b)(1))

- Before implementing moratoria, caps, or other limits, the SMA must determine that its action would not adversely impact beneficiaries' access to medical assistance. (§ 455.470(b)(2))
- The SMA must notify the Secretary in writing if it seeks to impose such moratoria, including all details of the moratoria, and obtain the Secretary's concurrence with imposition of the moratoria. (§ 455.470(b)(3))

Under § 455.470(c):

- The SMA must impose the moratorium for an initial period of 6 months. (§ 455.470(c)(1))
- If the SMA determines that it is necessary, the SMA may extend the moratorium in 6-month increments. (§ 455.470(c)(2)). Each time, the SMA must document in writing the necessity for extending the moratorium. (§ 455.470(c)(3)) This documentation must be made available to CMS for concurrence prior to the extension.

CMS must concur with any state-based moratorium. The SMA shall send any required requests for approval along with a completed CMS-10628 form for an Initial Request for State Implemented Moratorium under § 455.470 to ProviderEnrollmentMoratoria@cms.hhs.gov. The moratorium request, and moratorium extension request should be submitted to CMS at least 30 days in advance of the proposed effective date of the moratorium, or prior to the expiration of a moratorium.

Per 42 CFR 455.450(e), the SMA shall adjust the provider's categorical risk level from "limited" or "moderate" to "high," if the SMA lifts a temporary moratorium and a provider that was prevented from enrolling based on the moratorium applies for enrollment within 6 months from the date the moratorium is lifted.

The SMA shall contact CMS by email (ProviderEnrollmentMoratoria@cms.hhs.gov), to let CMS know whether it will lift the moratorium or will let it expire. If the SMA does not "lift" the moratorium but allows the moratorium to "expire", the SMA may, but, is not required to, elevate the provider's screening level to the "high" screening category. If the SMA chooses to elevate the provider's risk level it should document it. If the SMA lets the moratorium expire, the state should indicate in its email to CMS how the providers previously prevented from enrolling based on the moratorium will be enrolled and screened.

The SMA has considerable discretion regarding other aspects and parameters of administering such moratoria.

1.13 Medicaid and CHIP Managed Care Final Rule (CMS -2390-F)

1.13.1 Purpose

This section of the MPEC contains sub-regulatory guidance and clarification regarding how state Medicaid agencies (SMA) are expected to comply with the 2016 Medicaid and CHIP Managed Care Final Rule.

1.13.2 Applicability to Network Providers

A. General

Via the Final Rule published May 6, 2016 in the Federal Register, CMS applied provider screening and enrollment requirements to network providers participating in Medicaid Managed Care Entities (MCE), Prepaid Inpatient Health Plans (PIHP), and Prepaid Ambulatory Health Plans (PAHP). Regulations at 42 CFR § 438.602(b)(1) provide that the screening and enrollment requirements at 42 CFR Part 455 apply to all MCE network providers. Pursuant to this rule, network providers that furnish, order, refer, or prescribe must enroll with the SMA by January 1, 2018. This means that Medicaid MCE network providers who provide items or services to Medicaid beneficiaries will have to undergo the same screening and enrollment processes that Medicaid Fee for Service (FFS) providers are required to undergo in order to participate in the Medicaid program.

Although the original deadline for the enrollment of network providers was set to begin on July 1, 2018, Section 5005(b)(2) of the 21st Century Cures Act (Cures Act) superseded the May 6, 2016 rulemaking with respect to this deadline and established a new deadline of January 1, 2018. Please note that Prepaid Inpatient Health Plans (PIHP) and Prepaid Ambulatory Health Plans (PAHP) were not included in the Cures Act and as a result, are not held to that date and are instead held to the original deadline which is not later than the rating period for PIHP and PAHP contracts starting on or after July 1, 2018. See 81 FR 27499.

B. Definition of a Network Provider 42 CFR 438.2

A network provider is any provider, group of providers, or entity that has a network provider agreement with a MCE, PIHP, or PAHP, or a subcontractor, and receives Medicaid funding directly or indirectly to order, refer, or furnish covered services as a result of the state's contract with a MCE, PHIP, or PAHP.

States should determine whether an entity qualifies as a Managed Care entity by using the following definition found at 42 CFR 438.2. A "Managed care program means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act". See 42 CFR 438.2. Definition of Managed Care. If the delivery system is operated under the 1115(a) authority, states should consult the language within their waiver to determine whether the entity is referred to as managed care.

A network provider is not a subcontractor by virtue of the network provider agreement. More information regarding subcontractors may be found in the subcontractor section below.

Under 42 CFR 438.602(b)(1): The State must screen and enroll, and periodically revalidate, all network providers of MCEs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E. This requirement extends to Primary Care Case Managers (PCCMs) and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries.

C. Mechanisms for Identifying "In-Network" Providers

If SMAs gather provider data from the MCE for the purposes of determining who must enroll, it may be necessary for the SMA to request that the MCE identify those providers who are "innetwork" in that data, in order to determine which providers must be enrolled under § 438.602(b)(1).

1.13.3 Enrollment

Before discussing provider agreements, it may be useful to clarify the meaning of enrollment. Generally speaking, the screening process as governed by 42 CFR part 455, subparts B and E, which includes the collection of disclosures, is the precursor to enrollment with the State Medicaid Agency (SMA).

While there is no federally required enrollment application, all Medicaid providers are required to enter into an agreement with the SMA under 1902(a)(27) of the Act. See 81 FR 27601. CMS interprets the statutory reference to an "enrollment application" as the provider agreement with the state in the Medicaid context. See 81 FR 27601. This means that the enrollment of a network provider requires the completion of all screening requirements and the execution of a provider agreement with the state.

A. Screening vs. Credentialing

Under 42 CFR part 455, subparts B and E, screening is defined as a required element of the provider enrollment process effectuated via execution of a provider agreement between the state and the provider. Screening is used to determine whether an individual is eligible to

participate under the Medicaid state plan. Screening and enrollment includes, but is not limited to the activities under 42 CFR 438.602 (42 CFR 455 subparts B and E). For example, site visits, fingerprinting, checking NPPES, etc.

In contrast, under 42 CFR 438.214, credentialing is defined as the process conducted by the plan by which to verify whether the provider is qualified to perform or deliver services. This includes but is not limited to, the verification of a provider's education, training, liability record, and practice history.

A MCE plan may decline to enter into a network provider agreement with a provider that was otherwise screened and enrolled but did not meet the plan's credentialing criteria. For example, if a provider was seeking enrollment into the state Medicaid program and the provider meets all screening and enrollment requirements at 42 CFR 455 subparts B and E, but fails to meet the MCE's network credentialing requirements because they could not provide a National Specialty Board Certification, the MCE has the discretion to decline to enter into a network provider agreement with that provider. This denial would not preclude the provider from enrollment with the FFS program, unless the SMA has a similar criteria for eligibility.

B. Provider Agreements

Pursuant to the Final Rule, network providers in managed care entities are required to execute a provider agreement with the SMA. As explained in the final rule, enrollment means the SMA must execute a provider agreement with each network provider.

The SMA may want to consult with the MCE to ensure the network and state provider agreements do not contradict one another as network agreements may have their own fitness criteria that may or may not align with the SMA's.

Although the final rule requires execution of a provider agreement, 42 CFR 438.602(b) makes clear that execution of this agreement does not obligate the network provider to also render services to FFS beneficiaries. Therefore, SMAs may create separate provider agreements for network-only providers, which exclude language subjecting the provider to the acceptance of FFS Medicaid beneficiaries and other related requirements. For example, in the instance that a provider only wants to provide services in the Managed Care Entity, the SMA's current agreement may need to be modified to eliminate language that would require the provider to accept Medicaid FFS as payment, or language that requires publication of the provider in the Medicaid FFS provider directory.

Below are some examples of the types of contractual agreements the SMA might set up with a network provider in order to fulfill the enrollment requirement:

Example 1: The Final Rule requires the network provider to have an agreement with the SMA in place. CMS refers to this as the Medicaid Provider agreement – the agreement

executed between the network provider and the SMA. Some states may choose to utilize the same provider agreement used to enroll FFS providers.

Example 2: Network-only Provider Agreement – Some states may choose to utilize an agreement between the network provider and the SMA that allows a network provider to only provide services by participation in a network. This type of separate agreement allows a network provider to be excluded from providing furnishing services to FFS beneficiaries.

Example 3: Alternatively, some states may choose to utilize agreements that encourage network providers to provide services to FFS beneficiaries. A state may consider including a provision that prohibits the network provider from denying services to a beneficiary during the FFS eligibility window.

The use of more than one provider agreement is discretionary and may or may not be necessary depending on the SMA's current agreement.

MCEs may execute network provider agreements for up to 120 calendar days pending the completion of the screening required under 455 Subparts B & E. The MCE must terminate the provider's agreement and participation immediately upon: (1) expiration of the 120 day period when no enrollment decision is rendered by the SMA; or (2) notification from the SMA that the provider does not meet the state's enrollment requirements. Upon such termination, the MCE must notify affected enrollees.

C. Single Case Agreements

Per the 2016 Medicaid and CHIP Managed Care Final rule, "out-of-network" providers under single case agreements are not considered "network" providers and therefore are not subject to the requirements at 438.602(b). Out-of-network providers do not have to be screened and/or enrolled in the SMA's FFS program. Additionally, emergency room physicians are only subject to 438.602(b) to the extent they meet the definition of a network provider in 42 CFR 438.2.

D. Provider Types Not Enrolled by the SMA

Some MCEs enroll in their network provider types that are not eligible to enroll in the SMA FFS Medicaid program. The requirement for the SMA to enroll network providers does not extend to those network provider types who are not eligible to enroll in Medicaid FFS. However, states may consider requiring such provider types to enroll as a best practice. For example, states may choose to enroll provider types not otherwise eligible to enroll using an "Other" or "MCO-only" identifier.

Should a state decide to employ this practice, this would not obligate the state to make available to FFS beneficiaries services furnished by providers who are not eligible for FFS enrollment. In other words, the state maintains the discretion to determine which provider types are eligible to enroll in the FFS Program for purposes of providing furnishing services to FFS beneficiaries.

As an example, we are aware of a state that includes, within the benefits package of one of its MCEs, services rendered by dieticians. However, dieticians are a provider type ineligible to enroll in this state's FFS Program to furnish services to the state's FFS beneficiaries. In order to enroll dieticians with the SMA for purposes of strengthening program oversight, the state considered two options to incorporate the MCE's dieticians into the existing state enrollment database. First, the state considered creating a system identifier for the provider type "dietician." Having a specific identifier would enable the state to write targeted queries of the enrollment system later, to yield results specific to dieticians. The state ultimately decided against this approach, opting instead to create and use a more general identifier that they plan to use to designate any network provider type ineligible to enroll in FFS. The state felt using a general identifier might reduce the administrative burden of later adding additional provider types that are ineligible to enroll in the FFS program. Because this state had previously accomplished a system enhancement to disable reimbursement to certain providers, the state is able to enroll dieticians as providers ineligible for direct FFS reimbursement. This is a control that accomplishes enrolling the provider, but protects the program from risk of improperly paying the provider.

E. Ownership and Control Disclosures of Network Providers

The language at § 438.602(b) requires network providers be screened in accordance with the requirements located at Part 455 Subparts B and E. Network providers are thus subject to the disclosure of ownership and control interests requirements, located at Subpart B (§§ 455.100 through 455.106).

While § 438.602 provides SMAs the ability to delegate certain screening activities (discussed further in this guidance), the SMA's ability to delegate collection of disclosures is limited. Refer to Section 1.4.1.A.1.a. States should continue to follow the guidance found in Section 1.4.1 when developing a process for implementing the collection of disclosures of ownership and control interests for network providers.

1.13.6 Ordering or Referring Physicians or Other Professionals (ORP)

The requirement to enroll per § 438.602(b)(1) applies to all network providers and includes network providers who order or refer to other providers who provide services under the state plan or under a waiver of the plan. With respect to ORPs who only order or refer services for beneficiaries in managed care, this requirement does not extend to providers designated as

out-of-network or who do not meet the definition of network provider in 42 CFR 438.2. However, please refer to Section 1.3.B for guidance regarding providers that order or refer services to beneficiaries in the FFS population.

1.13.7 Exchanging Data between the Managed Care Entity and the SMA

States should consult with their MCEs to determine the specific data elements and file formats that are necessary to exchange enrollment data for the purposes of adjudicating claims. MCEs will need data from the states to ensure claims submitted by network providers enrolled with the SMA are paid appropriately. An example:

A SMA could develop system logic that includes the ability to edit encounter data that includes the determination of a provider's network status (whether they are "in" or "out" of network) in addition to the determination of the provider's enrollment status with the SMA (enrolled or not enrolled). The MCE would be responsible for identifying those providers who are "in-network" for SMAs to incorporate in their data, while the MCE would use the state's data to determine whether the provider is enrolled and properly submit any claims submitted by the providers.

States could include contractual language to facilitate the exchange of data between the MCEs and the SMA. This approach allows the SMA and the MCE to consistently define the appropriate data elements.

1.13.8 Out-of-Network Providers and Network Adequacy

States that contract with MCEs, PIHPs or PAHPs to deliver Medicaid services must develop and enforce network adequacy standards consistent with 42 CFR 438.68 and 438.206. To assist with these efforts states may, as a best practice, adopt encounter limits or thresholds that require out-of-network providers to convert to an in-network status, similar to the FFS guidance at Section 1.5.1.B.2.c. The FFS guidance is intended to establish thresholds for patient care activities that do not trigger the requirement for a state to directly enroll a provider into its own Medicaid FFS program. This guidance is intended to reduce burden to providers and state Medicaid agencies and promote patient access to care, while ensuring that all providers who service Medicaid beneficiaries are screened.

A SMA might determine, for example, that an out-of-network provider, upon reaching a specific threshold of encounters or services provided to a network beneficiary or beneficiaries, must be converted by the MCE to an in-network status for continued reimbursement by the network. Conversion to an in-network status would trigger the requirement for the provider to be screened and enrolled pursuant to 438.602(a)(1). In considering whether to apply such a policy, the state might explore factors including, but not limited to, identifying whether out-of-network provider claims represent a single instance of care or multiple instances of care,

beneficiary access, and whether a provider is successfully screened and enrolled in Medicare or in another state's Medicaid program.

1.13.9 In-Network Catchment Area Providers

In some regions a MCE's network may extend beyond the SMA's catchment area, i.e. a network provider could be located 5 states away from the SMA. Because beneficiary eligibility is predicated upon residing within the geographical boundaries of the state administering the Medicaid benefits, Medicaid beneficiaries are unlikely to receive services from those distant providers on a routine basis. Nonetheless, there may be instances where the beneficiary would need services, e.g., emergency services or services not available within the SMA's network of providers. SMA's are able to apply the enrollment exemption criteria within the MPEC. See MPEC Sections 1.5.1.C.2.a and 1.5.1.B.2.c. Using encounter data, the SMA should assess the number of instances of care furnished by the distant network provider in order to determine whether or not the particular provider should be enrolled. If the SMA identifies instances of care that exceed the 180 day threshold, it is likely the network provider should be enrolled.

States may also choose via contractual language, as a best practice to reduce provider burden, to redefine their MCEs' networks to include only those providers who furnish services to the state's Medicaid population or only those providers located within the state boundaries. Under this practice, the state would narrow the provider population subject to the enrollment requirement. However, the state should consider the impact this may have on beneficiary access to care.

1.13.10 Subcontractors

A subcontractor is an individual or entity that has a contract with an MCE, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCE's, PIHP's, PAHP's, or PCCM entity's obligations under its contract with the State.

When MCEs contract and enroll with the SMA, they are required to disclose subcontractors. For example, if a subcontractor is conducting educational outreach on behalf of the network for the purpose of promoting compliance with the requirement for network providers to enroll in the FFS program, although the subcontractor is not directly enrolling the provider or, billing the Medicaid program, because the subcontractor is indirectly doing work for the performance of the MCE's obligations under its contract with the SMA, the subcontractor is required to be disclosed by the MCE as a subcontractor of the MCE. Further, 438.602(d) requires the state screen all five percent or more owners and managing employees of subcontractors disclosed by the MCE.

1.13.11 Termination of Network Providers

With respect to termination of enrollment of network providers, SMAs should follow the same terminations and appeal procedures as required per sections 1.10 and 1.11.

1.13.12 Best Practices for Sharing Information about Terminated Providers

The SMA and MCEs will need to consider how to exchange information regarding the termination of providers. Similar to CMS' reporting of State Terminations and Medicare Revocations (made available via DEX), both the SMA and MCE should consider developing a centralized process that makes available information regarding termination action taken by the MCE or the SMA.

States should consider how often these reports will be generated and what data elements are necessary. For example, the SMA could develop a report of all termination actions they've taken and deliver it to the MCE on a monthly basis or the SMA could prescribe that the MCE report their terminated providers on an "as needed" basis. For those necessary data elements, CMS recommends states mirror the data elements currently described in section 1.10.4 (Medicaid Termination Reporting). This method could be achieved by the state including the requirement to report terminations in their contract language with the MCE. This is similar to the discussion under Section 1.13.17, "Exchanging Data between the Managed Care Entity and the SMA."

Ultimately, States should consider a mechanism that ensures that once termination action is taken on a provider, the MCE should no longer pay any claims for services furnished by that provider.

Attachment A

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

St	rate/Territory:
	4.46 Provider Screening and Enrollment
Citation 1902(a)(77) 1902(a)(39) 1902(kk); P.L. 111-148 and P.L. 111-152	The State Medicaid agency gives the following assurances:
42 CFR 455 Subpart E	PROVIDER SCREENING _Assures that the State Medicaid agency complies with the process for screening providers under section 1902(a)(39), 1902(a)(77) and 1902(kk) of the Act.
42 CFR 455.410	ENROLLMENT AND SCREENING OF PROVIDERS Assures enrolled providers will be screened in accordance with 42 CFR 455.400 et seq.
	Assures that the State Medicaid agency requires all ordering or referring physicians or other professionals to be enrolled under the State plan or under a waiver of the Plan as a participating provider.
42 CFR 455.412	VERIFICATION OF PROVIDER LICENSES Assures that the State Medicaid agency has a method for verifying providers licensed by a State and that such providers licenses have not expired or have no current limitations.
42 CFR 455.414	REVALIDATION OF ENROLLMENT Assures that providers will be revalidated regardless of provider type at least every 5 years.

42 CFR 455.416	TERMINATION OR DENIAL OF ENROLLMENT Assures that the State Medicaid agency will comply with section 1902(a)(39) of the Act and with the requirements outlined in 42 CFR 455.416 for all terminations or denials of provider enrollment.
42 CFR 455.420	REACTIVATION OF PROVIDER ENROLLMENT Assures that any reactivation of a provider will include re-screening and payment of application fees as required by 42 CFR 455.460.
42 CFR 455.422	APPEAL RIGHTS Assures that all terminated providers and providers denied enrollment as a result of the requirements of 42 CFR 455.416 will have appeal rights available under procedures established by State law or regulation.
42 CFR 455.432	SITE VISITS Assures that pre-enrollment and post-enrollment site visits of providers who are in "moderate" or "high" risk categories will occur.
42 CFR 455.434	CRIMINAL BACKGROUND CHECKS Assures that providers, as a condition of enrollment, will be required to consent to criminal background checks including fingerprints, if required to do so under State law, or by the level of screening based on risk of fraud, waste or abuse for that category of provider.
42 CFR 455.436	FEDERAL DATABASE CHECKS Assures that the State Medicaid agency will perform Federal database checks on all providers or any person with an ownership or controlling interest or who is an agent or managing employee of the provider.
42 CFR 455.440	NATIONAL PROVIDER IDENTIFIER Assures that the State Medicaid agency requires the National Provider Identifier of any ordering or referring physician or other professional to be specified on any claim for payment that is based on an order or referral of the physician or other professional.
42 CFR 455.450	SCREENING LEVELS FOR MEDICAID PROVIDERS Assures that the State Medicaid agency complies with 1902(a)(77) and 1902(kk) of the Act and with the requirements outlined in 42 CFR 455.450 for screening levels based upon the categorical risk level determined for a provider.

