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Part II

Department of Health and Human Services

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42 CFR Parts 405, 424, 447 et al.

Office of Inspector General

42 CFR Part 1007
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

Comment: One commenter suggested that the content of a fraud referral should be left to the discretion of each State. This commenter suggested that a continuing collaborative environment will fulfill the regulatory provisions regarding content of fraud referrals.

Response: We encourage States to collaborate with their MFCU. A fraud referral must contain, at a minimum, the elements as outlined in the proposed regulation and finalized here, but it is within a State's discretion to the extent it wishes to add additional information.

Comment: One commenter suggested that FQHCs should be exempted from the application of payment suspensions.

Response: We disagree. There is no statutory requirement to carve out an exception for any particular category of provider. We believe that payment suspensions apply to fraudulent conduct regardless of provider type.

Comment: One commenter suggested that payment suspensions should only apply to providers in the limited screening level, as that term is defined and used in connection with the provider screening rules, under only the most extraordinary circumstances.

Response: We decline to carve out an exception for providers in the limited screening level in the context of a payment suspension. This assignment to the limited level applies in the context of provider screening, not for suspension of payments. The determination regarding whether to impose a payment suspension is driven by credible allegations of fraudulent conduct and not whether a provider is assigned to a certain level for purposes of screening.

Comment: One commenter requested clarification regarding the application of payment suspensions to billing providers as opposed to prescribing providers. Another commenter requested a guarantee that payment suspensions will not be imposed against a billing provider.

Response: We understand that there are circumstances in which the prescribing provider may be different from the furnishing provider and/or billing provider. Generally, we believe that payment suspension is not the appropriate mechanism to recover Medicaid funds from one provider who inescapably, but innocently, happens to be associated with the fraudulent conduct of another provider. Because payment suspensions only apply based upon credible allegations of fraud, payment suspensions are generally not the appropriate vehicle by which to recover reimbursement for items and/or services furnished by a provider against whom there are no allegations of fraud. Nevertheless, there is no guarantee that a payment suspension will only be imposed against the billing provider as, particularly at the outset of an investigation of a credible allegation of fraud, it may be impossible to precisely determine the locus of the fraud or whether it involved collusion or conspiracy.

Comment: One commenter requested clarification regarding whether States with authority under existing State law may impose suspensions for reasons other than where there is a credible allegation of fraud. This commenter suggested that where such authority exists, the requirements proposed under § 455.23, including those concerning referrals to the MFCU and the duration of suspension should not apply.

Response: The requirements for payment suspensions under the proposed rule are based upon credible allegations of fraud. As we have noted several times in both these responses and in the proposed rule, nothing in these rules bar a State from exercising other broader authorities to suspend payments to providers.

We are adopting the provisions of the proposed rule with the exception of the following changes:

- In § 455.2, we have revised the definition of "credible allegation of fraud" to address the issue of the State's verification of the allegation.
- In § 455.23(a)(1), we have added the verbiage "after the agency determines there is a credible allegation of fraud for which" after the term "provider."
- In § 455.23(b)(2), we have added a new subsection (vi) that reads: "Set forth the applicable State administrative appeals process and corresponding citations to State law."
- In § 455.23(d), we have added the verbiage "has alternative Federal or State authority by which it may impose a suspension or" before "makes a fraud referral to another law enforcement agency."
- In § 455.23(e), we have revised subsection (3) to state: "The State determines, based upon the submission of written evidence by the individual or entity that is the subject of the payment suspension, that the suspension should be removed."
- In § 455.23(e), we have added a new subsection (6) that states: "The State determines that payment suspension is not in the best interests of the Medicaid program."
- In § 455.23(f), we have revised subsection (2) to read: "The State determines, based upon the submission of written evidence by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part."
- In § 455.23(f), we have added a new subsection (5) that states: "The State determines that payment suspension only in part is in the best interests of the Medicaid program."

E. Proposed Approach and Solicitation of Comments for Sections 6102 and 6401(a) of the Affordable Care Act —Ethics and Compliance Program

1. Statutory Changes

Under section 6102 of the ACA which established new section 1128I of the Act, a nursing facility (NF) or SNF shall have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care, consistent with regulations developed by the Secretary, working jointly with the HHS OIG. The regulations to establish the compliance and ethics program for operating organizations may include a model compliance program. The statute requires that in the case of an organization that has five or more facilities, the formality or specific elements of the program vary with the size of the organization. The statute also requires that not later than 3 years after the effective date of the regulations, the Secretary shall complete an evaluation of the programs to determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in the quality of resident care. The Secretary shall submit to the Congress a report on such evaluation with recommendations for changes in the requirements, as the Secretary deems appropriate.

Similarly, under section 6401(a) of the ACA, which established a new section 1866(j)(8) of the Act, a provider of medical or other items or services or a supplier shall, as a condition of enrollment in Medicare, Medicaid or CHIP, establish a compliance program that contains certain "core elements." The statute requires the Secretary, in consultation with the HHS OIG, to establish the core elements for providers or suppliers within a particular industry or category. The statute allows the Secretary to determine the date that providers and suppliers need to establish the required core elements as a condition of enrollment in Medicare, Medicaid, and CHIP. The statute requires the Secretary to consider the extent to which the adoption of compliance programs by providers or suppliers is widespread in a particular industry sector or particular provider or supplier category. Please note, NFs and

SNFs are subject to both compliance plan requirements under sections 6102 and 6401(a) since section 6401(a) of the ACA includes all providers and suppliers enrolling into Medicare, Medicaid and CHIP. We intend to establish compliance program core elements per section 6401(a) of the ACA for NFs and SNFs that closely match the required components of a compliance program per section 6102 of the ACA.

2. Proposed Ethics and Compliance Program Provisions

In order to consider the views of industry stakeholders, we solicited comments on compliance program requirements included in the ACA. We do not intend to finalize compliance plan requirements in this final rule with comment period; rather, we intend to do further rulemaking on compliance plan requirements and will advance specific proposals at some point in the future. We were most interested in receiving comments on the following:

The use of the seven elements of an effective compliance and ethics program as described in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual (*http://www.ussc.gov/2010guid/20100503_Reader_Friendly_Proposed_Amendments.pdf,* pp. 31–35) as the basis for the core elements of the required compliance programs for Medicare, Medicaid and CHIP enrollment. These elements instill a commitment to prevent, detect and correct inappropriate behavior and ensure compliance with all applicable laws, regulations and requirements, and include:

- The development and distribution of written policies, procedures and standards of conduct to prevent and detect inappropriate behavior;
- The designation of a chief compliance officer and other appropriate bodies (for example a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program and who report directly to high-level personnel and the governing body;
- The use of reasonable efforts not to include any individual in the substantial authority personnel whom the organization knew, or should have known, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program;
- The development and implementation of regular, effective education and training programs for the governing body, all employees, including high-level personnel, and, as appropriate, the organization's agents;
- The maintenance of a process, such as a hotline, to receive complaints and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;
- The development of a system to respond to allegations of improper conduct and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or Federal health care program requirements;
- The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
- The investigation and remediation of identified systemic problems including making any necessary modifications to the organization's compliance and ethics program.

In addition, we are particularly interested in comments about the following:

- The extent to which, and the manner in which, providers and suppliers already incorporate each of the seven U.S. Federal Sentencing Guidelines elements into their compliance programs or business operations. We are interested in how and to what degree each element has been incorporated effectively into the compliance programs of different types of providers and suppliers considering their risk areas, business model and industry sector or particular provider or supplier category.
- Any other suggestions for compliance program elements beyond, or related to, the seven elements referenced previously considering provider or supplier risk areas, business model and industry sector or particular provider or supplier category including whether external and/or internal quality monitoring should be a required for hospitals and long-term care facilities.
- The costs and benefits of compliance programs or operations including aggregate or component costs and benefits of implementing particular elements and how these costs and benefits were measured.
- The types of systems necessary for effective compliance, the costs associated with these systems and the degree to which providers and suppliers already have these systems including, but not limited to, tracking systems, data capturing systems and electronic claims submission systems. We anticipate having providers and suppliers evaluate the effectiveness of their compliance plans using electronic data.
- The existence of and experience with State or other compliance requirements for various providers and suppliers and foreseeable conflicts or duplication from multiple requirements.
- The criteria we should consider when determining whether, and if so, how to divide providers and suppliers into groupings that would be subject to similar compliance requirements including whether individuals should have different compliance obligations from corporations.
- Available research or individual experience regarding the current rate of adoption and level of sophistication of compliance programs for providers or suppliers based on their business model and industry sector or particular provider or supplier category.
- How effective compliance programs have been for varied providers and suppliers and how the level of effectiveness was measured.
- The extent to which providers and suppliers currently use third party resources, such as consultants, review organizations, and auditors, in their compliance efforts.
- The extent to which providers and suppliers have already identified staff responsible for compliance and, for those who already have staff responsible for compliance, the positions of these staff.
- A reasonable timeline for establishment of a required compliance program for various types and sizes of providers and suppliers, assuming the compliance program core elements were based on the aforementioned U.S. Federal Sentencing Guidelines' seven elements of an effective compliance and ethics program, considering business model and industry sector or particular provider or supplier category.

We welcomed any information concerning how the industry views compliance program elements and how we can establish required compliance program elements to protect Medicare, Medicaid, and CHIP from fraud and abuse.

3. Analysis of and Responses to Public Comment

We received numerous comments on compliance program elements in response to this request. Though we will not respond to those comments within this final rule with comment period, these will be considered for further rulemaking on compliance plan requirements.

4. Final Provisions—Ethics and Compliance Program

We are not finalizing these provisions in this final regulation. We are in the process of developing a new Notice of Proposed Rule Making incorporating the

compliance plan provisions and comments received that will be published at a later date. The proposed rule will also have an opportunity for further public comment.

F. Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

1. Statutory Change

Section 6501 of the ACA amends section 1902(a)(39) of the Act to require a State Medicaid program to terminate any provider, be it an individual or entity, participating in that program, subject to the limitations on exclusions in sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act, if the provider's participation has been terminated under title XVIII of the Act or another State's Medicaid program. Effective provider screening prevents excluded providers from enrolling in government health care programs and being paid with Federal and State funds. Effective screening of providers barred from participation can reduce the risk of fraud, waste, and abuse in the Medicare and Medicaid programs and CHIP

When a State terminates a provider but does not share that information with any other State, all other States become vulnerable to potential fraud, waste, and abuse committed by that provider. Similarly, a provider, supplier, or eligible professional that has been terminated from Medicare or has had Medicare billing privileges revoked may enroll with a State Medicaid program or with CHIP when a State is not aware of the Medicare termination or revocation. We may terminate or revoke the billing privileges of a provider, supplier, or eligible professional under Medicare for a number of reasons, as set forth at § 424.535, including exclusion from health care programs, government-wide debarment, and conviction of certain violent felonies and financial crimes.

Section 6501 of the ACA requires a State's Medicaid program to terminate an individual or entity's participation in the program (subject to certain limitations on exclusions in sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act), if the individual or entity has been terminated under Medicare or another State's Medicaid program. Although the term "termination" only applies to providers under Medicare whose billing privileges have been revoked (and does not apply to Medicare suppliers or eligible professionals), we believe it was the intent of the Congress that this requirement also be applicable to suppliers and eligible professionals that have had their billing privileges under Medicare revoked as well. Therefore, we proposed that "termination" be inclusive of situations where an individual's or entity's billing privileges have been revoked. The requirement for States to terminate would only apply in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause. "For cause" may include fraud, integrity or quality, but not cases where the providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked based upon voluntary action taken by the provider to end its participation in the program, except where that voluntary action is taken to avoid a sanction, or where a State removes inactive providers from its enrollment files.

In addition, State Medicaid programs would terminate a provider only after the provider had exhausted all available appeal rights in the Medicare program or in the State that originally terminated the provider or the timeline for such appeal has expired.

Section 6501 of the ACA builds upon the requirements in section 6401(b)(2) of the ACA, which requires that we establish a process to make available Medicare provider, supplier, and eligible professional and CHIP provider termination information to State Medicaid programs. Section 1902(kk)(6) of the Act also requires States to report adverse provider actions to CMS, including criminal convictions, sanctions, and negative licensure actions.

When States are apprised of the terminations or revocations of billing privileges, as the case may be, of providers, suppliers, and eligible professionals that have occurred in other State Medicaid programs, CHIP, or in Medicare, States have the information they need to protect their programs.

2. Proposed Provisions for Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

We proposed at § 455.416(c) that a State Medicaid program must deny enrollment or terminate the enrollment of a provider that is terminated on or after January 1, 2011 under Medicare, or has had its billing privileges revoked, or is terminated on or after January 1, 2011 under any other State's Medicaid program or CHIP.

While section 6501 of the ACA does not expressly require that individuals or entities that have been terminated under Medicare or Medicaid also be terminated from CHIP, we also proposed, under our general rulemaking authority pursuant to section 1102 of the Act, to require in CHIP regulations that CHIP take similar action to terminate a provider terminated or revoked under Medicare, or terminated under any other State's Medicaid program or CHIP.

We also proposed to add a definition at § 455.101 for termination for purposes of this section. That definition distinguishes between Medicaid providers and Medicare providers, suppliers, and eligible professionals and specifies that termination means a State Medicaid program or the Medicare program has taken action to revoke the Medicaid provider's or Medicare provider, supplier or eligible professional's billing privileges and the provider, supplier or eligible professional has exhausted all applicable appeal rights. There is no expectation on the part of the provider, supplier, or eligible professional or the State or Medicare program that the termination or revocation is temporary. The provider, supplier or eligible professional would be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

3. Analysis of and Responses to Public Comment

We received the following comments:

Comment: One commenter stated that while there is value to the States to have additional authority under which to deny or terminate Medicaid providers, it will be necessary to amend current statute and regulations to include new reasons for denials and terminations, and additional time will be required.

Response: In accordance with section 6508(b) of the ACA, a State may delay implementation of this provision if the Secretary determines that State legislation is required.

Comment: Commenters asked for clarification regarding ACA section 6401(b)(2) that requires CMS to establish a process to make available Medicare provider, supplier, and eligible professional and CHIP termination information to State Medicaid programs. Commenters asked if a mechanism was in place for States to check for terminated providers starting January 1, 2011. One commenter requested clarification as to how State Medicaid programs would communicate with Medicare contractors when the States had revoked or suspended a Medicaid enrollment. Another commenter asked if the Provider Enrollment, Chain, and Ownership System (PECOS) would be

distinct and potentially costly process for criminal background checks through private entities that, we believe, will probably not involve access to the scope of data that the FBI has.

We believe that the overall costs involved in maintaining such a two-part approach would, in the end, exceed that of the FBI IAFIS approach, especially if—as we expect—the overwhelming majority of individuals subject to the fingerprinting requirement submit them electronically. Indeed, with respect to the cost differential between the paper and electronic fingerprinting processes, we stated earlier in the RIA that we estimate an average annual cost of the fingerprinting requirement of $2,275,000 (if 2,000 post-moratorium requests are made), based on: (1) The fingerprinting of 45,500 individuals; and (2) a $50 cost per person for obtaining a set of fingerprints via the FD–258. We believe that the per person cost for submitting fingerprints electronically will be approximately $35. If we assume that 40,000 of the 45,500 individuals submit fingerprints electronically and the remaining 5,500 use the FD–258, this results in an annual cost of $1,675,000, or $600,000 less than $2,275,000. This leads to a savings over 5 years of $3,000,000 ($600,000 × 5).

It is not possible for us to quantify the costs involved in having the FBI IAFIS perform the criminal background checks. However, we can estimate that it would cost approximately $40 per person to perform a criminal background check via private entities. This would result in an annual cost of $1,820,000, or $9,100,000 over 5 years. With the efficiency furnished through the use of the FBI–IAFIS, we do not believe the cost of these checks would ultimately exceed $9,100,000.

We concede that the submission of a passport or tax return would not involve the processing costs that would come with fingerprinting. But the ability to verify one's identity via fingerprinting is, we believe, sufficiently greater than with the latter two documents, such that the overall program integrity savings would substantially exceed any additional cost incurred in using fingerprints in lieu of passports and tax returns.

3. Other Suggested Alternatives

We received several other suggested alternatives to our proposed provisions. One was to assess the application fee based on the NPI or TIN. As stated earlier in this RIA, we did not believe this approach was appropriate because the requirement to submit an enrollment application is separate from the requirement to have an NPI or a TIN. We believe that basing the fee on the submission of an application is most consistent with the statute. Another involved taking into account factors such as: (1) Error rates; (2) past history with Medicare, Medicaid and other health plans; and (3) ownership, when assessing a provider or supplier's risk. In section II of this final rule with comment period, we stated that the ACA requires levels of screening according to the risk of fraud, waste, and abuse posed by categories of providers and suppliers as a whole. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by risk of fraud, waste, and abuse is consistent with the requirements of the statute. Therefore, in general, we chose to use a categorical approach to our classifications, rather than assign individual providers within a particular provider type to certain risk levels.

F. Conclusion

This final rule with comment period contains provisions that are of critical importance in the transition of CMS' antifraud activities from "pay and chase" to fraud prevention. "Pay and chase" refers to the traditional approach under which we met our obligations to provide beneficiaries access to qualified providers and suppliers and to pay claims quickly by making it relatively easy for providers to sign up to bill Medicare, Medicaid or CHIP, paying their claims rapidly, and then detecting overpayments or fraudulent bills and pursuing recoveries of overpayments after the fact. That system functions reasonably well when the problems arise with legitimate providers and suppliers that will be solvent and in business when CMS seeks to recover overpayments or law enforcement pursues civil or criminal penalties. It is not adequate when the fraud is committed by sham operations that provide no services or supplies and exist simply to steal from Medicare or Medicaid and thrive on stealing or subverting the identities of beneficiaries and providers.

This final rule with comment period strikes a balance that will permit us to continue to assure that eligible beneficiaries receive appropriate services from qualified providers whose claims are paid on a timely basis while implementing enhanced measures to prevent outright fraud. The new and strengthened provisions in the ACA that are the subject of this final rule with comment period will help assure that only legitimate providers and suppliers are enrolled in Medicare, Medicaid, and CHIP, and that only legitimate claims will be paid. These provisions are applied according to the level of risk of fraud, waste, and abuse posed by different provider and supplier types. We will use screening tools for a particular provider or supplier type based on 3 distinct categories of risk: (1) Limited; (2) moderate; and (3) high. Limited risk providers will have enrollment requirements, license and database verifications; moderate risk will have those verifications plus unscheduled site visits; high risk will have verifications, unscheduled site visits, criminal background check and fingerprinting. CMS and the States will impose moratoria on the enrollment of new providers in situations when doing so is necessary to protect against a high risk of fraud. Working in conjunction with the OIG, CMS and States will suspend payments pending an investigation of a credible allegation of fraud and legitimate providers will be assisted in avoiding problems by implementing effective compliance programs.

This final rule with comment period is an essential tool in protecting public resources and assuring that they are devoted to providing health care rather than enriching fraudulent actors.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.