these provisions will largely be accomplished through measures such as State Program Integrity reviews conducted by CMS. Such reviews will, among other things, evaluate States' complaint intake and investigation efforts, and assess whether States have an effective process to move matters where there are found to be credible allegations of fraud to the point where they are evaluated for payment suspension. However, we do not believe it is viable to require States to report and document to CMS every instance of where any allegation of fraud arises and further qualify which ones rise to the level of credible allegation. We want to foster effective and efficient State program integrity efforts with respect to which payment suspension is an integral component, but we do not want to create a system so procedurally onerous that it overwhelms a State's ability to substantively perform this critical work. Nevertheless, we will thoroughly investigate and act by, among other things, deferring and/or disallowing FFP in accordance with § 430.40 and § 430.42, if program integrity reviews or other methods of ensuring State compliance with Medicaid program requirements reveal a State is failing to suspend payments (or inappropriately applying a good cause exception) where pending investigations of credible allegations of fraud do exist. A State may not claim (on its Form CMS–64) FFP for payments that are suspended. Any State that does not suspend payments, or that suspends payments but continues to claim FFP with respect to what would have been paid had no suspension been in place, puts that FFP at risk. In such cases, we would pursue a deferral and/or disallowance to reclaim the Federal portion of such payment. We solicit comments on CMS' proposed oversight approach.

Finally, three provisions are proposed to be added to the regulations at § 1007.9 that specify the State MFCU's relationship to, and agreement with, the State Medicaid agency. These proposed revisions are necessary to effectuate the proposed revisions under § 455.23. The regulations at 42 CFR part 1007 are enforced by HHS OIG as part of its delegated authority to certify and fund the State MFCUs. (*See* August 15, 1979 final rule (44 FR 47811)). However, we are including amendments to part 1007 here to ensure a comprehensive regulatory package that sets forth in one location the Department's implementation of the suspension provisions of section 6402(h) of the ACA.

The first of these provisions proposes to add a new paragraph (e) to § 1007.9 that specifies that the MFCU may refer to the State agency any provider against which there is pending an investigation of a credible allegation of fraud for purposes of payment suspension in accord with § 455.23. Allegations of potential fraud may first be identified by the MFCU rather than by the State agency, so this provision merely formalizes a path from the MFCU to the State agency so a payment suspension may be implemented where appropriate. This provision also proposes that any referral to the State agency for consideration of a payment suspension be in writing. The written referral need not be extensive, but must include information adequate to enable the State agency to identify the provider and a brief explanation of the credible allegations forming the grounds for the payment suspension. The second proposed addition to § 1007.9 proposes to add a new paragraph (f) providing that any request by the unit to the State agency to delay notification of suspension to a provider pursuant to the provisions of the proposed § 455.23(b)(1)(ii) come in writing. Proposing to require that such requests need be made in writing (which could take the form of an e-mail) provides for an audit trail to ensure that proper procedures are followed. However, we expressly do not intend for this requirement to create any substantive right upon which a provider might lodge objection or other legal challenge to the extent the proper procedures were not followed. Last, a new paragraph (g) is proposed to require the unit to notify the State agency in writing when it has accepted or declined a case referred by the State agency. Aside from also creating an audit trail, this proposed provision would be important in that it would alert the State agency as to the status of a referral, which would shape how the State agency would handle a suspension under the proposed revisions to § 455.23.

### *E. Proposed Approach and Solicitation of Comments for Sections 6102 and 6401(a) of the ACA—Ethics and Compliance Program*

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 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.

In order to consider the views of industry stakeholders, we are soliciting comments on compliance program requirements included in the ACA. We do not intend to finalize compliance plan requirements when the other proposals in this proposed rule are finalized; rather, we intend to do further rulemaking on compliance plan requirements and will advance specific proposals at some point in the future. We are 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 above 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 welcome 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.

*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. Discussion

Effective provider screening prevents excluded providers from enrolling in government health care programs and being paid with Federal and State funds. Providers barred from participating because of effective screening cannot abuse Medicare, Medicaid, or 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 violent felonies and financial crimes.

Section 6501 Affordable Care Act 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)(2)(B) and 1128(d)(2)(B) of the Act), if the individual or entity has been terminated under Medicare or