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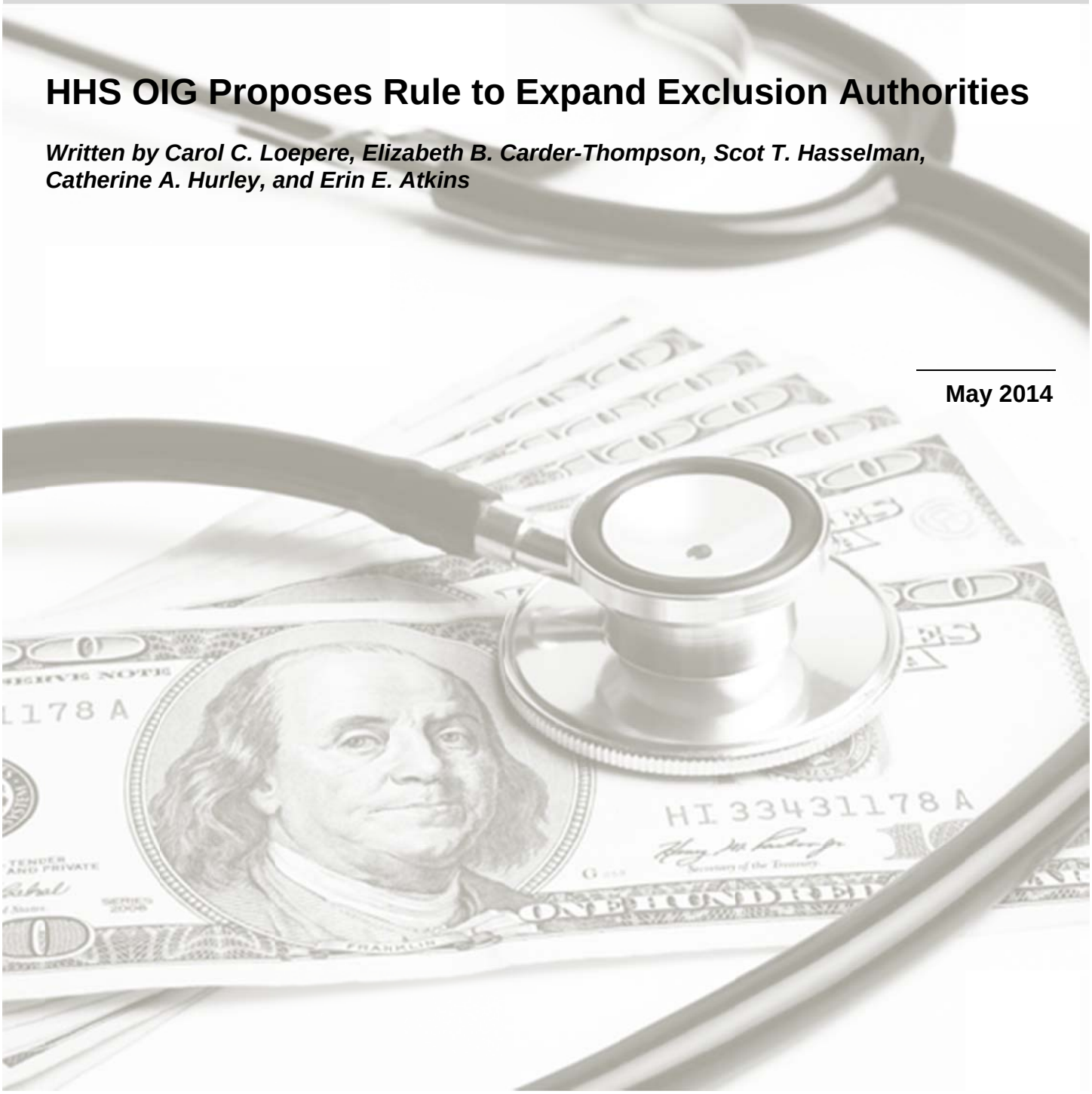
HHS OIG Proposes Rule to Expand Exclusion Authorities

Written by Carol C. Loepere, Elizabeth B. Carder-Thompson, Scot T. Hasselman, Catherine A. Hurley, and Erin E. Atkins



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On May 9, 2014, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published a proposed rule that would significantly expand the exclusion regulations applicable to persons or entities that receive, directly or indirectly, funds from federal health care programs (the Proposed Rule).[1] The Affordable Care Act (ACA) expanded the OIG's authority for exclusion and authorized the use of testimonial subpoenas in investigations of exclusion cases. In this Proposed Rule, the OIG incorporates these statutory changes, revises the definitions applicable to exclusions, proposes early reinstatement procedures, and offers a number of proposed policy changes as to when and how exclusions may take place.

This Client Alert provides an overview of the Proposed Rule, including:

- The proposed revisions in the definitions
- The three new grounds for exclusion
- Clarifications to existing regulations to add mitigating and aggravating factors
- The proposed early reinstatement procedures
- Proposed procedural changes in the OIG's exclusion authorities[2]

In particular, we discuss the OIG's assertion that there should be *no* statute of limitations within which it would have to seek exclusion. This limitless look-back authority could place a tremendous burden on providers and suppliers, since their conduct and compliance efforts could be second-guessed many years into the future, when supporting documentation and witnesses may be long gone. We also discuss how these proposed changes to

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1 79 Fed. Reg. 26810 (May 9, 2014), available at http://www.gpo.gov/fdsys/pkg/FR-2014-05-09/pdf/2014-10390.pdf.

2 Notably, on May 10, 2014, the OIG published another proposed rule to amend its civil monetary penalty (CMP) rules to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on penalties, assessments, and exclusions. *See* http://www.gpo.gov/fdsys/pkg/FR-2014-05-12/pdf/2014-10394.pdf. Among other things, the CMP rule proposes an "alternative methodology" for calculating a penalty amount for excluded persons who do not directly submit claims to federal health care programs. Reed Smith is preparing a separate Client Alert on this proposed rule. The OIG states that these rules are part of a broader package of regulations addressing the OIG's fraud and abuse authorities, and that it contemplates additional rulemaking involving inflation adjustment for CMPs, safe harbors under the anti-kickback statute, a revised definition of remuneration, and a codified gainsharing CMP. Each of the proposed rules is a stand-alone, independent rule, however, and the public need not wait for all of the proposed rules to be published to submit comments on any one of the proposed rules. Nonetheless, we believe it is important to review the exclusion and CMP-proposed rules together, given the overlapping and interrelated nature of these proposed program integrity initiatives.

the OIG's exclusion authorities could impact the debarment authority applicable to government contracts more generally.

Comments on the Proposed Rule are due *July 8, 2014*.

I. Background and Overview

The OIG identifies the underlying purpose of the exclusion authorities as protecting the federal health care programs and their beneficiaries from "untrustworthy health care providers, i.e., individuals and entities who pose a risk to program beneficiaries or the integrity of these programs."[3] Section 1128 of the Social Security Act (the Act) provides the OIG with two categories of exclusion authority: mandatory and permissive.

1. *Mandatory exclusions* (section 1128(a) of the Act) are required for any individual or entity convicted of a "program-related crime," such as patient abuse or neglect, and certain felonies related to health care delivery, governmental programs, and controlled substances. Mandatory exclusions last at least five years, and can result in permanent exclusion.

2. *Permissive exclusions* (section 1128(b) of the Act) permit the OIG to exclude individuals and entities for a broad range of conduct. Permissive exclusions, in turn, consist of two types: (1) "derivative" exclusions, i.e., those that are based on actions previously taken by a court or other law enforcement or regulatory agency; and (2) "affirmative" exclusions that are based on the OIG's own initiative and administrative action for misconduct, such as poor quality care, kickbacks, submission of false claims, and other program integrity matters. Permissive exclusions have no five-year minimum, and can vary in duration. Importantly, an excluded person is not permitted to participate in federal health care programs until the excluded person is officially reinstated.

While the OIG has offered certain mitigating factors to be considered in imposing permissive exclusions, and it proposes new early reinstatement procedures, the OIG, on balance, would greatly expand the bases upon which it could affirmatively exclude an individual or entity from program participation.

II. Changes in Definitions

The OIG proposes what it describes as "technical" revisions to certain key definitions to streamline the regulations and reduce confusion. Specifically, the OIG would modify the definitions of "furnished," "directly," and "indirectly."[4] These proposed changes, which demonstrate the OIG's extremely broad interpretation of its exclusion authority, are as follows:

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[3] 79 Fed. Reg. at 26811.

[4] The OIG also proposes to expand its definition of "state health care program" to include any "child health plan approved under Title XXI (Children's Health Insurance Program)." The current definition includes only Medicaid, title V (Maternal and Child Health Services Block Grant) programs, and title XX, subtitle A (Children's Health Insurance Program) programs. This revised definition would be relocated from 42 C.F.R. § 1001.2 to 42 C.F.R. § 1000.107.

"Furnished"

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity~~. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services~~.

"Directly"

Directly, as used in the definition of "furnished" in this section, means the provision or supply of items and services by individuals or entities (including items and services provided or supplied by them, but manufactured, ordered, or prescribed by another individual or entity) who ~~submit claims to~~ request or receive payment from Medicare, Medicaid, or other Federal health care programs.

"Indirectly"

Indirectly, as used in the definition of "furnished" in this section, means the provision or supply of items and services manufactured, distributed, supplied, or otherwise ~~supplied~~ provided by individuals or entities ~~who~~ that do not directly ~~submit claims to~~ request or receive payment from Medicare, Medicaid, or other Federal health care programs, but that provide items and services to providers, practitioners, or suppliers who ~~submit claims to~~ request or receive payment from these programs for such items and services~~. This term does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.~~

Notably, the OIG explains that replacing the phrase "submit claims to" with "request or receive payment from" in the definitions of "directly" and "indirectly" would be consistent with the "broad" definition of "claim" in the False Claims Act,[5] and would "appropriately encompass all current and future payment methodologies." With respect to its proposal to add "provided" after "or otherwise" in the definition of "indirectly," the OIG explains that it has "always interpreted the definition . . . to cover any employee or contractor of a provider that receives payment" from federal health care programs.

The OIG would also establish new regulatory definitions for certain terms that are currently defined either by cross referencing the statute or in an explanatory clause. For example, in the current regulations, the term "ownership or control interest" is accompanied in many (but not all) instances with the parenthetical "(as defined in section 1124(a)(3) of the Act)."[6] The OIG proposes to remove these parenthetical references, and would instead

[5] 31 U.S.C. 3729(b)(2).

[6] *See* e.g., 42 C.F.R. § 1001.101(d)(2).

establish a definition for "ownership or control interest" in the "definitions" section at 42 C.F.R. 1001.2, mirroring the statutory definition.[7]

Finally, the OIG would relocate, without material modification, a number of its definitions, including "exclusion," "agent," "immediate family member," "indirect ownership interest," "member of household," and "ownership interest," and delete certain definitions[8] that are not relevant to the OIG's exclusion or other rules.

III. Expanded Exclusion Authority

The Proposed Rule would create new regulations authorized by the ACA to expand greatly the OIG's permissive exclusion authority. Notably, the ACA authorizes permissive exclusions for: (i) conviction of an offense in connection with the obstruction of an audit; (ii) failure of a person who "order[s], refer[s] for furnishing, or certify[ies] the need for" items or services to supply specific payment information; and (iii) making any false statement, omission or misrepresentation of a material fact in an application to participate as a provider or supplier in a federal health care program.

1. Conviction related to obstruction of an audit or investigation

Currently, the permissive exclusion regulations allow the OIG to exclude an individual or entity that has been convicted in connection with interference in or obstruction of an investigation into any criminal offense that is the basis for mandatory exclusion, or that is the basis of a permissive exclusion based upon program or health care fraud. The ACA expands the OIG's authority to permit exclusion (1) when the conviction involves either the obstruction of an investigation or *the obstruction of an audit* related to any criminal offense that is a basis for mandatory exclusion or permissive exclusion, or (2) when the investigation or audit relates to the use of federal health care program funds received by the individual or entity, either directly or indirectly.

The Proposed Rule would revise 42 C.F.R. § 1001.301 to implement this ACA change by adding references to "audit." In addition, the Proposed Rule would add a monetary aggravating factor that the OIG could consider when determining the length of the exclusion to be imposed. The new aggravating factor would allow the OIG to extend the exclusion beyond the current three-year exclusion period if (1) the act or similar acts that resulted in the underlying obstruction conviction caused a financial loss of $15,000 or more to a government agency or program, or (2) the underlying act(s) had a significant financial impact on program beneficiaries or other

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[7] Likewise, the definition of "managing employee" would be listed up front among the definitions at 1001.2, instead of within the regulations discussing it.

[8] These definitions are currently located at 42 C.F.R. §§ 1000.20 and 1000.30.

individuals. The practical effect of these proposed changes would be that an audit, which could be relatively informal in nature, would be considered on par with a formal investigation for exclusion purposes.

2. Failure to provide payment information

Current regulations allow the OIG to exclude "any individual or entity that furnishes items or services for which payment may be made" under Medicare or Medicaid who fails to provide certain payment information related to those services. The ACA expands the OIG's authority to apply this basis for exclusion not only to the provider or entity *directly furnishing* the services, but also to any individual or entity "ordering, referring for furnishing, or certifying the need for" items or services.

The Proposed Rule would codify this authority at 42 C.F.R. § 1001.1201. The practical effect of the change would be to dramatically expand the number of providers and/or entities that could be subject to exclusion for failure to provide certain payment information. Not only would the actual provider of services be susceptible to possible exclusion, but other providers and/or entities who did not actually render the services at issue also could face scrutiny. Thus, the OIG could seek to exclude an ordering or referring physician, or a person who merely certified that services were medically necessary for a beneficiary but who did not bill for the item or service in question.

3. Making false statements or misrepresentation of material facts

The ACA also established a new basis for permissive exclusion for any individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract, to participate or enroll as a provider of services or supplier under a federal health care program.

The Proposed Rule would add new regulations at 42 C.F.R. § 1001.1751 to implement this new provision. In order to ascertain whether an alleged false statement or omission related to a "material" fact, the OIG would define "material" as something that has "a natural tendency to influence or be capable of influencing the decision to approve or deny" the enrollment application. The OIG states vaguely that it would decide to impose such an exclusion "on the basis of information gathered from various sources, including but not limited to," CMS, state Medicaid agencies, contractors, private insurance companies, state or local licensing or certification authorities, law enforcement agencies, and "any other source deemed appropriate by the OIG." The OIG would be allowed to consider mitigating factors when determining the length of any possible exclusion period, such as the repercussions of the false statement and whether the individual or entity had a documented history of criminal, civil, or administrative wrongdoing. The Proposed Rule provides no details or explanation of how the OIG would actually interact with the various "sources of information" listed in the proposed regulation, nor is there any discussion relating to the catch-all category of "any other source deemed appropriate by the OIG." Note that the

proposed new authority would apply not only to provider *enrollment* applications, but also to agreements, bids, and contracts with federal health care programs.

IV. Changes to Existing Exclusion Authority

1. Exclusion Based on Certain Types of Convictions

The OIG proposes to narrow its "derivative" exclusion authority for individuals or entities that have been convicted of certain criminal offenses, felonies, and controlled-substance misdemeanors. Specifically, under 42 C.F.R. § 1001.101 (describing the OIG's mandatory exclusion authority) and under 42 C.F.R. § 1001.401 (describing the OIG's permissive exclusion authority based on controlled-substance convictions), the OIG proposes to restrict its exclusion authority only to those individuals and entities *currently* furnishing health-related items and services, or those who were so involved *at the time of the offense*, as opposed to those who *have ever*, met this description. Thus, the Proposed Rule announces the OIG's policy to exclude only those individuals or entities committing the predicate offense while such individual or entity was a health care practitioner, provider, or supplier, who furnished items or services, or who owned, was a managing employee of, or was employed in any capacity in the health care industry.

2. Aggravating and Mitigating Factors

The OIG reviews a variety of factors in determining the appropriate length of an exclusion. If "aggravating factors" are present that the OIG believes justify lengthening the period of exclusion (e.g., if the underlying offense has resulted in a significant monetary loss to a federal program), it can seek to lengthen an exclusion period. Only after reviewing the possible aggravating factors does the OIG then look to see if "mitigating factors" are present that would justify shortening the exclusion period.[9]

The Proposed Rule would modify several of these factors, in different kinds of proceedings:

1. *Derivative exclusions for license revocation/suspension*: The OIG proposes to eliminate consideration of aggravating and mitigating factors for "derivative" exclusions based on license revocations or suspensions,[10] and based on exclusion or suspension under a state health or another federal health care program.[11] As a practical matter, the exclusion periods in such cases are usually

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[9] The OIG has exceptions to its system of considering aggravating and mitigating factors (as applicable) to determine the appropriate length of the exclusion period for: (1) permissive exclusions for false or improper claims at 42 C.F.R. § 1001.901, and (2) permissive exclusions for fraud, kickbacks, and other prohibited activities a 42 C.F.R.§ 1001.951. If proceeding under these exclusion authorities, the OIG has retained more flexibility by listing more general factors that the OIG will consider in determining the appropriate length of the exclusion period.

[10] 42 C.F.R. § 1001.501.

[11] 42 C.F.R. § 1001.60.

co-terminus with the duration of the license revocation/suspension, or the program exclusion/suspension. The Proposed Rule would make this general practice part of the regulations.

2. *Beneficiary access ("alternative sources") no longer a mitigating factor*: Currently, the OIG can consider as a mitigating factor whether "alternative sources" of the type of health care item or service furnished by the individual or entity to be excluded are available to beneficiaries (presumably, in a given community). The OIG proposes that beneficiary access appropriately is a factor in deciding whether an exclusion should be *waived*, but not in determining the *length* of an exclusion.[12] Thus, under the proposed rule, individuals or entities subject to most types of permissive exclusion proceedings would no longer be able to argue that "beneficiary access" justifies a shorter exclusion period.

3. *Monetary thresholds*: Finally, the OIG proposes to update the monetary thresholds used in aggravating and mitigating factor consideration.[13] Aggravating factors that pertain to financial loss to the government or federal health care programs[14] would be updated to include a $15,000 (rather than a $5,000 or $1,500) threshold – an amount the OIG characterizes as "a realistic marker for determining whether someone is untrustworthy." Similarly, the mitigating factor at 42 C.F.R. § 1001.102(c)(1) (allowing for a shorter period of mandatory exclusion if the predicate conviction resulted in a total financial loss to the government of less than $1500) would be updated to $5,000.[15]

i) Exclusion of Individuals with Ownership or Control Interest in Sanctioned Entities

Under 42 C.F.R. § 1001.1051, the OIG can exclude individuals with direct or indirect ownership or control interests in entities that have been convicted of certain offenses or subject to certain program-related terminations or exclusions if they knew or should have known about the entity's improper actions. The OIG proposes to use the same exclusion period for the individual and the entity in such cases, even if the individual terminated his or her relationship with the sanctioned entity.

ii) Failure to Grant Immediate Access

Under 42 C.F.R. § 1001.1301, the OIG may exclude individuals or entities that fail to grant "immediate access" (as defined) upon a reasonable request, to the secretary of HHS, a state survey agency, a state Medicaid fraud control unit, or the OIG to carry out specified program oversight and other functions. The current provision references access to "records, documents and other data"; under the Proposed Rule, the OIG could consider exclusion for failing to grant access to many more sources of information, including "records, documents, and other material or data in any medium (including electronically stored information and any tangible thing) necessary to the OIG's statutory functions."

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12 *See, e.g.*, 42 C.F.R. § 1001.201(b)(3)(iv).

13 42 C.F.R. §§ 1001.102(b)(1), 1001.102(c)(1), 1001.201(b)(2)(i), & 1001.701(d)(2)(iv).

14 42 C.F.R. §§ 1001.102(b)(1), 1001.201(b)(2)(i), 1001.701(d)(2)(iv).

15 The OIG would also make certain clarifications to the scope of this mitigating factor, which the OIG states does not apply where the predicate act involved abuse and neglect (because financial loss is irrelevant), or where the predicate act is required to be a felony (because this factor only considers whether financial loss from misdemeanor offenses exceed the dollar threshold).

V. Early Reinstatement

In one of the few provisions in which the OIG proposes to lessen burdens on individuals subject to exclusion, the OIG proposes a new process for "early reinstatement." This process would apply only to *individuals* (not entities) who have been excluded under section 1128(b)(4) of the Act. This proposal is intended to liberalize and shorten the process through which an individual can be reinstated in participation in federal health care programs. This is significant not only for individuals directly billing federal health care programs (e.g., physicians), but also for any individuals seeking employment or desiring to enter contractual arrangements with health care providers. We would note that, under the Proposed Rule, the individual would still be required to meet the current rules for reinstatement and demonstrate to the satisfaction of the OIG that reinstatement did not prevent a risk to federal health care programs or beneficiaries.

By way of background, the OIG can and does exclude individuals or entities whose state health care license has been revoked or suspended by a state licensing authority, or who have otherwise lost or surrendered such a license or the ability to apply for or renew a license for reasons bearing on professional competence, performance, or financial integrity. Under current law, an individual excluded under section 1128(b)(4) is not eligible to be reinstated until the license that was originally lost is restored in the same state in which it was lost. In other words, the exclusion from federal health care program runs co-terminus with the licensure revocation, suspension, or surrender.

The OIG acknowledges that it excludes a "significant number" of individuals as a result of loss of state licensure. Many of these individuals lose their licenses permanently, move to a different state, or choose not to obtain a new license. Under current regulations, this effectively results in a permanent exclusion even if the individual was not charged or convicted of a criminal offense, and could even be the result of administrative or clerical lapses (e.g., a name change, missing a renewal deadline) that have no bearing on the individual's trustworthiness. As a result, the OIG is proposing to amend the regulations for exclusion for license revocation or suspension (§ 1001.501) to add a new section (c), pertaining to "Early Reinstatement." This new section would have two subparts, depending upon whether the excluded individual obtains a new health care license:

1. *If individual obtains a new license*. An excluded individual could request early reinstatement if, after fully and accurately disclosing the circumstances surrounding the original license action that formed the basis for the exclusion, the individual obtained the same health care license that was lost (as under current law), was allowed to retain a health care license in another state, or retained a different health care license in the same state.

2. *If individual does not obtain a new license.* An excluded individual could request early reinstatement if he or she did not have a valid health care license of any kind, provided that the individual could demonstrate that he or she would no longer pose a threat to federal health care programs.

The OIG proposes to consider a variety of factors in determining whether to grant a request for early reinstatement, including, among others, the circumstances that formed the basis for the exclusion; evidence that the second licensing authority was aware of the circumstances; and whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action.

Note that the early reinstatement process would supplement, rather than replace, the existing reinstatement regulations at § 1001.3002(b). Specifically, the individual would still have to, among other things, provide reasonable assurances that the actions that formed the basis for the exclusion have not recurred and will not recur, pay any fines and debts due and owing (including overpayments), obtain CMS determination that the individual met the applicable conditions of participation or supplier conditions, and show that he or she has not submitted or caused to be submitted any claims to federal health care programs while the individual was excluded.

Moreover, an individual who is not seeking a health care license and has been excluded for less than five years would need to overcome the presumption against reinstatement. We observe that this proposed presumption may be misplaced. The OIG provides no explanation regarding why it is proposing a higher bar for someone seeking a nonlicensed position, especially since a person in a nonlicensed position generally has less or no direct role in furnishing or billing for items or services paid by federal health care programs. Consider, for example, a therapist who was excluded because he lost his state physical therapy license because of substance addiction. The therapist seeks treatment and is found to have addressed his addiction. Two years later, he decides to apply for a position as a scheduling clerk or warehouse worker at medical device company. Under the OIG's proposal, this excluded individual could have to wait five years to have the exclusion lifted and be hired in the health care field because he would not be eligible for early reinstatement.

The OIG states that it is also considering alternative approaches, and solicits comments on these and any additional factors that should be considered.

VI. Statute of Limitations on Affirmative Exclusions

In what doubtless will be the most controversial aspect of the proposal, the OIG enunciates an expansive interpretation of its exclusion authority to assert that there is *no* statute of limitations on affirmative exclusions imposed under section 1128(b)(7) of the Act for false or improper claims. As a result, the OIG proposes adding a new section to the effect that "an exclusion is neither time barred nor subject to any statute of limitations period, even when the exclusion is based on violations of another statute that might have a specific limitations period."

This is the second time that the OIG has attempted to amend its regulations to provide that there would be no limitations period on its ability to impose exclusions under 1128(b)(7) of the Act. In 2000, the OIG issued a

proposed rule that would have done the same thing.[16] Commenters questioned this interpretation, pointing out that if an exclusion is based on the OIG's determination that there has been a violation of another statute, the program exclusion action should be subject to the same limitations period that would apply to an action taken under the other statute. Otherwise, an individual or entity could be excluded for activities that occurred years before and that do not bear on current trustworthiness or integrity. In addition, the commenters expressed concern that after the passage of significant time, evidence becomes difficult or impossible to gather, underscoring the need for limitations on program exclusions. Based upon these concerns, the OIG decided in 2002 *not* to adopt the proposed revision in the regulations.[17]

Twelve years later in the Proposed Rule, the OIG has attempted to revive the same proposal. The OIG offers little new grounds for its position, despite its contention that "strong policy and legal justifications" support its interpretation that no limitations period should apply. Specifically, the OIG observes that section 1128 of the Act regarding false or improper claims does not include a limitations period. The OIG also simply asserts that even though an exclusion action may be based upon another violation of law that contains a limitations period under section 1128(b)(7) of the Act (e.g., a CMP action), that does not mean that same limitation period should apply. In the preamble to the Proposed Rule, the OIG states that the agency does not believe the passage of time will prejudice the person subject to the exclusion. Further, the OIG claims that since many of these actions arise in the context of related civil False Claims Act proceedings – which are often resolved significantly later than the six years after the underlying conduct – the OIG cannot know until the case is settled whether the provider will agree to pay appropriate restitution, fines or penalties, and adopt "appropriate compliance measures" (i.e., enter into a Corporate Integrity Agreement or similar document), thus potentially mitigating against exclusion. If there were a six-year statute of limitation, the OIG asserts, the agency would be forced to file exclusions actions prematurely, thus requiring the OIG, the defendant and the Departmental Appeals Board (DAB) to devote resources to a case that otherwise might settle. The OIG also states that filing an exclusion action while a False Claims Act investigation or settlement discussion is pending may disrupt the civil case. Therefore, the OIG claims it is appropriate to consider exclusion based on conduct that is more than six years old.

Despite the OIG's arguments as to why it believes the agency must have the ability to seek exclusion for false or improper claims at any time, the concerns expressed by the commenters during the 2000-2002 rulemaking remain valid today. Over time, the ability to retain evidence and the availability of witnesses significantly decreases. The OIG's Proposed Rule could require health care and life science companies to maintain records well beyond the time periods required by the Medicare and Medicaid programs. Further, the proliferation of civil

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16 *See* 65 Fed. Reg. 63035 (Oct. 20, 2000).

17 *See* 67 Fed. Reg. 11928, 1929 (March 18, 2002).

False Claims Act cases over the past decade could lead to a similar explosion in exclusion actions. While the OIG states that in most cases "it makes sense" for the OIG to decide whether to impose an exclusion based on the facts and circumstances at the time of the potential settlement, there is no requirement in the Proposed Rule that the OIG wait until the settlement. The OIG could bring a parallel exclusion action at any time for conduct in the distant past. Finally, if the exclusion authority is in fact remedial, the OIG has not demonstrated how imposing exclusion for conduct occurring many years earlier that likely involved different people, policies, and procedures, furthers that policy goal.

VII. Procedural Changes: Waiving Exclusions, Scope and Effect of Exclusion, Subpoenas, and Opportunity to Present Oral Argument

The Proposed Rule would implement a number of procedural changes impacting the OIG's exclusion process in order to codify recent statutory directives contained in the Medicare Modernization Act (MMA) and the ACA. Specifically, the Proposed Rule would (i) expand the circumstances under which a health care administrator may request an exclusion waiver, (ii) update the regulatory provisions governing scope and effect of exclusion, (iii) provide additional opportunity for individuals or entities subject to potential exclusion to request oral argument, and (iv) increase the OIG's authority to subpoena testimony. The Proposed Rule would provide more consistency between the OIG's statutory authority and its implementing regulations.

The current version of the regulations addressing when exclusions can be waived entirely has not been updated since prior to the enactment of the MMA. The regulations currently permit state health care program administrators to request an exclusion waiver involving program-related crimes when the individual or entity subject to the exclusion is the *sole community physician* or the *sole source of essential specialized services* in a given community. The Proposed Rule would update the regulations in several ways. First, it would authorize waiver requests for felony convictions related to health care fraud and controlled substances. Additionally, the Proposed Rule would replace references to state health care program administrators with federal health care program administrators. Finally, the Proposed Rule would update the hardship standard to conform to the statute, allowing an administrator of a federal health care program to request a waiver if the administrator believes that the exclusion would impose a hardship on any beneficiary eligible to receive items or services under a federal health care program, *and* the provider subject to the exclusion is the sole community physician or sole source of essential specialized services in a given community.[18]

The OIG also proposes several changes to the regulations addressing the scope and effect of an exclusion, found at 42 C.F.R. § 1001.1901. Among other things, the Proposed Rule would expand the application of the current

[18] The MMA changed the standard to permit a waiver request if the exclusion would impose a hardship on a Medicare beneficiary. The ACA updated the standard to include *any* beneficiary of a federal health care program.

regulations to Medicare Parts C and D (Medicare Advantage and Prescription Drug Plans, respectively). The OIG also seeks comments on creating a limited exception to the general prohibition against paying for items or services ordered by an excluded physician where the enrollee and the pharmacy did not know that the prescribing physician was excluded. Under current law, the Centers for Medicare & Medicaid Services (CMS) will pay Part B claims submitted by a Medicare enrollee when the items or services are furnished by an excluded individual if the enrollee does not know or have reason to know of the exclusion. Medicare must notify the enrollee of the exclusion, and not pay claims after a reasonable time after such notification. By expanding application of this rule to claims payable under Medicare Parts C and D, the OIG recognizes that unique situations may arise when Part D drug claims are involved. In that scenario, Medicare will notify the beneficiary that the physician ordering the prescription is excluded, and will not pay claims ordered by that physician after the beneficiary has received reasonable notice. However, as a practical matter, in the Part D context, this notice is not very helpful since enrollees rarely submit claims directly to Medicare. Rather, the dispensing pharmacy submits the claims. The OIG interprets the law to bar Medicare payments to the pharmacy for items prescribed by an excluded physician after a reasonable time period after notice to the pharmacy of the physician's exclusion. The OIG concludes, "This statutory prohibition appears to apply regardless of whether the enrollee is aware of the exclusion." As a result, the OIG seeks public comment on how to protect enrollees in this situation who may urgently need medications and not know that the prescribing physician is excluded.

Additionally, the Proposed Rule would extend the opportunity for individuals and entities subject to exclusion to request and present oral argument. Current regulations permit oral argument before the OIG for exclusions because of excessive charges or unnecessary services, or failure to furnish medically necessary services. The OIG proposes also to permit oral arguments for exclusions as a result of false statements or misrepresentations of material facts in documents related to a federal health care program.

Finally, the Proposed Rule would update the regulations to reflect the OIG's statutory authority to subpoena testimony in potential exclusion investigations. Prior to the ACA, the OIG's testimonial subpoena authority was limited to circumstances in which the OIG was pursuing CMPs under section 1128A of the Act. The ACA expanded the OIG's authority to instances where the OIG pursues exclusions for both permissive and mandatory exclusions under section 1128. As such, OIG proposes updating its regulations to reflect this statutory change.

VIII. Implications of Exclusion for Debarment from Government Contracts

Conduct that can lead to OIG exclusion can generally also form the basis for a suspension or debarment. The proposed changes to the exclusion regulations would not, however, alter the government's authority to initiate suspension or debarment against an individual or entity not deemed "presently responsible" (that is, who is determined not to meet the government's criteria related to contractors' capabilities and conduct). Accordingly, individuals or companies defending against a mandatory or permissive exclusion should also consider the

suspension and debarment risk. While the OIG's exclusion authority relates to federal health care programs, suspension and debarment are much broader government-wide actions and are not just limited to federal health care programs. When a contractor is suspended, proposed for debarment, or debarred, the contractor cannot receive new contract awards. Further, for existing contracts, the government cannot make new orders (beyond minimum ordering thresholds), add new work, or otherwise extend the contract. The government retains wide discretion in determining whether a contractor should be suspended or debarred, with different criteria than the OIG's exclusion criteria. For instance, causes for suspension and debarment include a conviction of or civil judgment pertaining to committing fraud or a criminal offense related to public contracts, violating the terms of a government contract or subcontract, and any other facts adversely impacting a contractor's present responsibility. Mitigating that risk may involve making a proactive present responsibility presentation to the appropriate agency suspending and debarring official as to why suspension or debarment is not appropriate.

IX. Conclusion

The Proposed Rule would greatly strengthen the OIG's exclusion authority, by both expanding the grounds for exclusion and broadening the reach to additional entities, and for longer timeframes. The OIG has been responsive to thoughtful public comment on this issue in the past; thus the comment period provides an important opportunity for affected parties to analyze and weigh in on the scope of this authority.
