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Table of Contents

FIDA: New York's Financial Alignment Demonstration for Dual-Eligible Beneficiaries

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In Section 3021 of the Affordable Care Act (ACA), the U.S. Congress established the Center for Medicare & Medicaid Innovation to develop and test innovative health care payment and delivery models.[1] One such model allows states to test and evaluate the provision of fully integrated care for individuals who are dually eligible for Medicaid and Medicare, known as dual eligibles.[2] On August 26, 2013 New York State entered into a Memorandum of Understanding (MOU) with the Centers for Medicare & Medicaid Services (CMS) to implement a capitated model of care designed to lower costs and improve quality of care for dual eligibles.[3] CMS also has approved financial alignment models in several other states, including Massachusetts, Washington, Ohio, Illinois, California, Texas, and Virginia.[4] These pilot projects will be used to determine whether the alignment of Medicare and Medicaid can achieve better health care outcomes for dual eligibles and lower program costs through improvements in coordinated care.

Under New York's model, known as the Fully Integrated Duals Advantage (FIDA) Demonstration (Demonstration or FIDA Demonstration), the New York State Department of Health (NYSDOH) and CMS will enter into three-way contracts with managed long term care plans (MLTC Plans) to provide, either directly or through subcontracts, the full range of items and services covered by the Medicaid and Medicare programs.[5] Approximately 170,000 dual eligibles in New York City, Long Island, and Westchester will have an opportunity to participate in the Demonstration, now scheduled to run from January 1, 2015 through January 1, 2017.[6] CMS will then undertake an independent evaluation of New York's model, along with the models of the other participating states, to assess the quality of care received by participating enrollees, the effects on utilization and cost savings, and other factors bearing on the viability of the initiative.[7]

This article provides an overview of the FIDA Demonstration, including the payment structure and participant protections, and it considers how the Demonstration simplifies the processes for dual eligibles to access the items and services to which they are entitled under Medicaid and Medi-

care. To understand the impetus for this effort by CMS and New York, the article will first review the financial misalignment in the current payment system and how cost-shifting between Medicare and Medicaid adversely affects the quality and cost of health care for dual eligibles. Although the FIDA Demonstration offers the promise of fixing a broken system, it remains to be seen whether the initiative will attract sufficient interest from stakeholders to deliver on that promise.

Dual Eligibles: Trapped in a Broken System

Dual eligibles are individuals who qualify for Medicaid and Medicare.[8] Thus, by definition, they are poor and either elderly, disabled, or both. They are a vulnerable and challenging population of beneficiaries who consume a disproportionate share of both programs' spending.[9] In 2008, dual eligibles made up 20% of the Medicare population but accounted for 31% of all Medicare spending.[10] Similarly, dual eligibles represented 15% of the Medicaid population but accounted for 39% of program spending.[11] In 2005, Medicare and Medicaid spending per dual eligible averaged more than $20,000, about five times more than the average spending on other Medicare beneficiaries.[12]

The high cost of providing care to dual eligibles is directly related to their significant health care needs and higher utilization of services.[13] A majority of dual eligibles have complex health conditions and chronic illnesses that require the full range of Medicaid and Medicare benefits.[14] Compared to other Medicare beneficiaries, they have higher rates of hospital visits, emergency room visits, and skilled nursing facility (SNF) admissions. To address their diverse needs, dual eligibles must enroll in multiple health care plans and navigate a multitude of rules, benefits, insurance cards, providers, and administrative obstacles.

Dual eligibles rely on Medicare as their primary insurer to cover acute care services, such as hospitalization, and post-acute care at SNFs. Medicare also covers durable medical equipment, prescription drugs, X-ray and laboratory services, physician services, and outpatient and other services.[15] In addition, most dual eligibles rely on Medicaid as a secondary insurer to pay Medicare premiums and cost-sharing and to cover services not covered by Medicare, such as dental, vision, transportation to and from providers, mental health care, and therapy. Dual eligibles also rely on Medicaid to cover long term care not covered by Medicare, such as custodial nursing facility care, coverage for skilled nursing care once Medicare benefits are exhausted, home and community-based services, and personal care services.[16] Through the Medicare-Medicaid initiatives, federal and state governments seek to provide dual eligibles with a better care experience by making it easier for them to navigate the convoluted path to covered services.

Dual eligibles are trapped in the middle of a bifurcated system with separate streams of financing, reimbursement rates, and coverage rules. The confluence of the two programs creates conflicting incentives and encourages cost-shifting among state and federal governments and health care providers. As a result of cost-shifting, dual eligibles are unnecessarily transferred between settings and receive highly fragmented and uncoordinated care. This disruption increases the likelihood of medical errors, medication mismanagement, and susceptibility to disease and infection, and generally undermines quality of care. In short, under the status quo, "Medicare and Medicaid simply pass the buck to one another, leaving the patient and the taxpayer to absorb the consequences."[17]

Conflicting Incentives and Cost-Shifting Under the Status Quo

Under the current system, cost-shifting abounds. Whether Medicaid or Medicare will cover a particular benefit depends on a variety of differing eligibility criteria including, for example, statutory and regulatory definitions of medical necessity and judicial decisions related to scope of coverage. Oftentimes, the boundaries of coverage are blurred, and determining who the responsible payer is can be difficult.[18] This ambiguity is subject to manipulation and invariably leads to cost-shifting between the programs.

Some states have adopted policies to make Medicare the primary payer of services whenever possible, a strategy known as "Medicare Maximization."[19] These Medicare Maximization policies include contracting with private entities to conduct Medicare Maximization or Third-Party Liability audits to identify claims that the Medicare program should have, but did not, pay; filing claims on behalf of beneficiaries and pursuing appeals if coverage is denied; and educating providers on billing techniques to shift costs to Medicare.[20] There is little incentive for states to adopt policies to reduce unnecessary hospitalizations, short-stay nursing home admissions, or emergency room visits, most of which are paid for by Medicare, because any savings to the federal government under Medicare would concomitantly result in increased costs for state governments under Medicaid. The current payment system promotes cost-shifting practices over cost-sharing practices, which adversely affects the delivery of health services to dual eligibles and inflates the overall burden on taxpayers.

An example of cost-shifting often cited among policymakers occurs when long-stay nursing home residents are hospitalized. More than one quarter of long-stay nursing home residents are transferred to a hospital at some point during the course of any given year, and the rate is rising.[21] The cost of avoidable hospitalizations for this subpopulation of beneficiaries is substantial.[22] Medicare could save hundreds of millions of dollars annually if treatment were provided in a nursing home, rather than in a hospital, in appropriate

cases.[23] However, there are financial barriers to providing acute care in nursing homes. Due to inadequate reimbursement rates, many nursing homes lack the financial and clinical resources required to treat more acutely ill residents and instead hospitalize out of necessity, most commonly for pneumonia, flu, and dehydration. This practice artificially inflates the total cost of care because it is normally less expensive to treat these conditions in nursing homes than in hospitals.[24] States, for their part, have little incentive to increase reimbursement rates or invest in policies to reduce unnecessary hospitalizations and emergency room visits of long-stay nursing residents because, absent cost-sharing arrangements, any savings achieved through such state-funded policies would flow almost exclusively to the federal government.[25]

This state of affairs is unfortunate because increases in reimbursement rates and staffing levels directly correlate with decreases in avoidable hospitalizations. For example, a $10 increase in the daily Medicaid reimbursement rate for nursing home care has been shown to reduce avoidable hospitalizations by between 5% and 9%.[26] In addition, higher reimbursement rates are related to increases in staffing (which, again, tends to reduce avoidable hospitalizations).[27] One solution to this cost-shifting problem is cost-sharing. In cost-sharing, the state or the provider would share in the savings from reductions in Medicare-covered services.

This tug-of-war between Medicare and Medicaid creates inefficiencies in the delivery and payment of services to an already vulnerable population. The financing system surrounding dual eligibles leads to disjointed and fragmented care and places patients at unnecessary risk of developing complications.[28] FIDA offers a solution, as participating plans will be responsible for managing a fixed sum of money to meet the health care needs of enrollees. To provide services to dual eligibles on a tighter budget, FIDA plans will have to use financial incentives to encourage providers to develop innovative alternatives to high-cost services. The assumption of risk by the FIDA plans is expected to promote the objectives of the Demonstration by eliminating cost-shifting between Medicaid and Medicare and by coordinating care for dual eligibles.

Overview of the FIDA Demonstration

The MOU entered into between NYSDOH and CMS sets forth the terms and conditions the parties intend to incorporate into the three-way contracts,[29] which the parties are currently in the process of negotiating (Draft Contract). As reflected in the MOU and Draft Contract, the FIDA Demonstration's key objectives are to promote independence in the community, deliver person-centered care, eliminate cost-shifting between Medicaid and Medicare (discussed above), improve participant experience in accessing care, and achieve cost savings through improvements in care and coordination.[30]

The Demonstration will focus on dual eligibles with long term care needs, whether they receive support services in the community or in a facility.[31] Dual eligibles who qualify for the Demonstration include individuals: (1) 21 years old or older at the time of enrollment; (2) entitled to Medicare Part A benefits; (3) enrolled in Medicare Parts B and D; (4) who receive full Medicaid benefits; and (5) who reside in one of eight counties in the Demonstration geographic service area.[32] Although the current MOU specifically excludes individuals receiving supports and services from the New York State Office for People With Developmental Disabilities and residents of, or individuals qualified for residing in, intermediate care facilities for individuals with intellectual/developmental disabilities,[33] a separate proposal from New York State, which intends to test a comparable model for beneficiaries with intellectual/developmental disabilities, is pending before CMS.[34]

The majority of eligible participants are already enrolled in one of the MLTC Plans seeking to participate.[35] The participating plans will modify their offerings and create an integrated plan to cover all Medicaid- and Medicare-covered services.[36] The FIDA Demonstration's start date was initially scheduled for July 1.[37] However, due to delays related to implementation activities, such as readiness reviews and rate completion, NYSDOH and CMS agreed to postpone the start date to January 1, 2015.[38] Readiness reviews include review tools to address key areas that directly impact a beneficiary's ability to receive services including, but not limited to, assessment processes, care coordination, provider network, staffing, and systems to ensure that the organization has the capacity to handle the increase in enrollment of the complex Medicare-Medicaid enrollee population.[39] The criteria also focus on whether a FIDA plan has the appropriate participant protections in place, including whether the FIDA plan has policies that adhere to the Americans with Disabilities Act, uses person-centered language and reinforces beneficiary roles and empowerment, reflects independent living philosophies, and promotes recovery-oriented models of behavioral health services.[40] With the exception of a handful of plans participating in Medicare Advantage, the experience of MLTC Plans in New York is limited almost exclusively to the Medicaid context. For example, MLTC Plans have not had to negotiate with hospitals, physicians, and other providers necessary for the development of networks. Also, to prolong matters even more, the Draft Contract is a behemoth at 381 pages.

Participants will be enrolled into the FIDA Demonstration under two different timetables: One for individuals receiving community-based services and another for individuals receiving facility-based care.[41] Eligible individuals will be notified of the program and will be able to start enrolling 60 days in advance of the effective date. Eligible individuals who do not enroll in a plan or who do not affirmatively opt

out will be automatically and "passively" enrolled into a FIDA plan.[42] Individuals can opt out of the Demonstration at any time and return to Medicare fee-for-service or Medicare Advantage coverage, or they can select another FIDA plan. Neither the state nor CMS has the authority to require dual eligibles to be "locked in" to plans, and, therefore, the Demonstration has a risk of either insufficient participation or of such movement from plan to plan that the value of care coordination and other mechanisms intended to improve care and reduce costs will not be effective.

The concept of passive enrollment has drawn criticism from stakeholders. However, unlike MLTC Plans in New York, enrollment in a FIDA plan is optional. Consistent with patient rights under Medicare, eligible participants have the right to choose whether they want to participate in the FIDA Demonstration, and if so, in which plan and provider network they enroll.[43] If participants are dissatisfied with their coverage and care, they can exercise their rights to disenroll or transfer between FIDA plans on a month-to-month basis throughout the term of the Demonstration. Enrollments, opt-outs, and transfers will be effective on the first day of the following month.[44]

For purposes of continuity of care, participants will have access to all providers, all authorized services, and preexisting service plans for 90 days after enrollment or until a comprehensive assessment has been completed and a service plan is developed, whichever comes later.[45] All FIDA plans must enter into contracts or have payment arrangements with all nursing homes in the Demonstration area so that passively enrolled nursing home residents have continuity of care for the duration of the Demonstration.[46]

New York State must contract with an independent entity to serve as an ombudsman to help participants access care through their FIDA plans, understand and exercise their rights and responsibilities, appeal adverse coverage decisions, and provide general information and advice in dealing with plans and providers.[47] The ombudsman will provide free assistance and will be available by phone or in person.[48]

Under the Demonstration, CMS and NYSDOH will withhold a percentage of their respective portions of the total capitated payment, excluding Part D amounts. The plan will be able to "earn back" the withheld amount by meeting certain quality thresholds, such as access and availability, care coordination/transitions, health and wellbeing, mental and behavioral health, patient/caregiver experience, screening and prevention, and quality of life.[49] Time will tell whether the quality withholds will serve their intended purpose and encourage the participating plans to improve care outcomes for enrollees. Even if the financial incentive is not enough to influence behavior, perhaps the public relations incentive will be, as any failure by the plan to meet the quality thresholds will be disclosed to the public.[50]

One central feature of the Demonstration is the integrated grievance and internal appeals process.[51] Under FIDA, the Medicaid and Medicare grievance and internal appeals processes will be consolidated into a single system with a single set of rules comprising the most participant-friendly elements of the Medicare and Medicaid systems. "Aid continuing" will be granted in all appeals, provided that the appeal is filed within ten days, and all adverse appeal decisions will be automatically forwarded to the Integrated Administrative Hearing Office at the Office of Temporary and Disability Assistance.[52]

New York opted to participate in the FIDA Demonstration under a capitated model of financing. Under this model, the participating plans will receive a prospective blended payment (on a per-member, per-month basis) to provide, either directly or through subcontracts, the full range of items and services covered by the Medicaid and Medicare programs.[53] The state and federal government will contribute proportionally to the total capitated payment based on a formula consisting of an annual saving percentage and a baseline spending amount.[54] The annual savings percentage is fixed and represents the anticipated savings to the programs through improvements in care coordination. The annual savings percentage is set at 1% in the first year, 1.5% in the second year, and 3% in the third year (subject to reduction).[55] The respective state and federal contributions will be determined by applying the annual savings percentage to the baseline spending amounts. The annual savings percentage will be applied equally to the baseline spending amounts, and, therefore, NYSDOH and CMS will share in the savings realized by the Demonstration regardless of the underlying utilization patterns. Although the savings percentages are fixed (for the most part), the baseline spending amounts are variable. CMS has defined baseline spending amounts as "an estimate of what would have been spent in the payment year had the demonstration not existed. Baseline spending will be established prospectively on a year-by-year basis for each demonstration county."[56]

The formula for determining the state and federal portions of the total capitated payment does not account for utilization patterns and ensures New York will benefit economically from participating in the initiative even if, as expected, the savings primarily accrue to the Medicare program from reductions in unnecessary hospitalizations and emergency room visits. This form of cost-sharing discharges much of the financial friction between the programs. However, to the extent the baseline spending amounts will be adjusted to reflect shifts in costs to Medicaid and Medicare under the FIDA Demonstration, the incentive to cost-shift may remain.

Conclusion

Section 3021 of the ACA attempts to confront the rising costs of providing care to dual eligibles without jeopardizing quality of care. The FIDA Demonstration provides solutions to many of the problems in the current system. The ability of capitation and the assumption of risk by participating plans serve to promote the goals of the Demonstration and could, in theory, improve quality of care for dual eligibles.

That said, FIDA may not be successful unless the stakeholders are on board. The major stumbling block to full implementation is that enrollment in the FIDA program is not mandatory. FIDA allows enrollees to opt out whenever they want and go back to what they had before. Although FIDA enrollees will have access to all the services they need, they will become part of a limited network of providers, and many will have to break relationships with longstanding providers who are fully familiar with their medical histories. Early enrollment numbers for states participating in the initiative are not encouraging. In California, for example, as of July 1, only 40,000 out of 450,000 qualifying individuals have opted in, and an equal number have made an active decision not to participate.[57] Similarly, in Massachusetts, as of May 1, the opt-outs outweigh the opt-ins by a margin of 38%.[58] The numbers elsewhere are similar.[59] According to the results of a focus group, eligible individuals are reluctant to participate because they are afraid of losing their providers and facing new restrictions on services.[60] As with other aspects of the ACA, the trick may be finding the right way to market the initiative to the public. Otherwise, these pilot programs may never take flight.

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Permissive Exclusion: OIG Proposes Rule Creating More Problems, Not Solutions for Long Term Care Providers

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Long term care providers, already subject to economic pressures, may be impacted by proposed changes introduced by the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG). OIG issued a Proposed Rule on May 9 with the purpose of implementing expanded authority to protect federal health care program beneficiaries from fraud and abuse.[1] The Affordable Care Act (ACA)[2] and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[3] primarily authorized the proposed amendments. Three days after the release of the Proposed Rule related to OIG's exclusion authority, OIG released a companion piece on the Civil Monetary Penalty (CMP) Rules.[4] The Proposed Rule, presented as an improvement on current exclusion procedures, imposes significant compliance concerns and obligations for long term care providers.

OIG's Authority to Exclude

The Secretary of HHS (Secretary) has delegated authority to OIG to exclude, from participation in Medicare, Medicaid, and other federal health care programs, individuals and entities that have engaged in fraud or abuse. OIG also may impose CMPs for certain misconduct related to federal health care programs.[5] Congress established the Civil Monetary Penalties Law (CMPL) to authorize HHS and OIG to impose CMPs, assessments, and program exclusions against any person who submits false, fraudulent, or certain other types of improper claims for Medicare or Medicaid payment.[6] "Claims submitted by an excluded person for items or services furnished during the person's exclusion violate the CMPL."[7]

OIG's authority extends to both mandatory[8] and permissive[9] exclusions. OIG is required to exclude from federal health care program participation any individual or entity convicted of a "program-related" crime,[10] a crime related to patient abuse or neglect,[11] or one of a list of specific felonies related to health care delivery, governmental health care programs, or controlled substances.[12] Mandatory exclusions are for a minimum period of five years.[13]

On the other hand, with "permissive" exclusion, the Secretary has some discretion in determining whether to exclude providers for certain other offenses. Permissive exclusion occurs one of two ways: (1) "derivative" exclusions in which the exclusion is based on actions previously taken by a regulatory agency, such as a health care licensing board, a court, or a law enforcement agency; or (2) "affirmative" exclusions based on OIG-initiated determinations of misconduct. The examples of affirmative conduct provided in the commentary to the Proposed Rule include poor quality of care, kickbacks, and submission of false claims to a federal health care program.[14]

In Fiscal Year (FY) 2013, HHS excluded 3,214 individuals and entities from participation in federal health care programs.[15] For the first half of FY 2014, OIG has excluded 1,720 individuals and entities.[16] CMPs associated with these exclusions also have yielded the OIG substantial recoveries. Each year from 2004–2013, OIG collected between $10.2 million and $26.2 million in CMP resolutions for a total of more than $165.2 million.[17]

The ACA and OIG's Expanded Exclusion Authority

The ACA authorized many of the proposed amendments expanding OIG's permissive exclusion authority. The ACA provides that permissive exclusion may be imposed for the following:

- Conviction of an offense in connection with the obstruction of an audit;[18]
- Failure to supply payment information;[19] and
- Making, or causing to be made, any false statement, omission, or misrepresentation of a material fact in applications to participate as a provider of services or supplier under a federal health care program.[20]

These proposed changes significantly expand OIG's authority, and, despite OIG's intention to make life easier for providers by creating a mechanism for "early reinstatement" of certain providers, the net increase in regulatory burden remains substantial.

No Statute of Limitation to OIG's Exclusion Authority

OIG proposes to add language eliminating the time limit within which to seek exclusion "even when the exclusion is based on violations of another statute that might have a specific limitations period."[21] In discussing the current proposal, OIG considered CMP actions which have a statute of limitations of six years:

> We agree that, as a general matter, recent acts are more indicative of current trustworthiness than acts that took place in the distant past. Nevertheless, we believe that conduct that is more than 6 years old may sometimes form a proper basis to conclude that a person should be excluded. The age of the conduct is a factor in determining

> the weight the conduct should be afforded, not whether the exclusion should not be imposed at all. We do not believe the passage of time will prejudice the person subject to exclusion.[22]

While conceding that recent acts are more indicative of current trustworthiness, OIG's proposed changes are contrary to this statement. OIG claims that if Section 1128(b)(7) of the Social Security Act is subject to a six-year statute of limitations, then it will be forced to file exclusion actions prematurely.[23] OIG also claims that many False Claims Act (FCA) cases are resolved through settlement or litigation much later than six years after the underlying conduct and that OIG does not make a determination to seek exclusion until the settlement terms have been decided or there is a judgment.[24] In further support of its position, OIG claims that filing exclusion actions during the pendency of an FCA investigation or settlement discussion may disrupt the civil case.[25]

The elimination of a time limit potentially opens the OIG's exclusion authority to extend back indefinitely. In effect, OIG's proposed elimination of a limitations period substantially increases the potential for periods of exclusion. The imposition of exclusion may happen many years after underlying matters have transpired and been resolved. The evidence in the underlying matter may no longer be accessible or in existence at the time of exclusion, even taking into account extended record-retention policies based on a litigation hold.

The Proposed Rule Purports to Provide "Early Reinstatement"

The Proposed Rule includes a ray of hope for excluded individuals. First, the Proposed Rule would amend the reinstatement rules to permit excluded persons to seek reinstatement in a more expeditious manner "when appropriate."[26] Second, the Proposed Rule would remove "aggravating and mitigating factors" relating to exclusions based on the loss of a health care license.[27] These proposed amendments represent OIG's response to hardships reported by providers, including situations in which exclusions for relatively minor licensing issues become more permanent than exclusions issued for more-serious offenses. The ray of hope, however, may be a false one.

OIG proposes a process for the early reinstatement of individuals excluded under Section 1128(b)(4) of the Social Security Act. Under the current law, many individuals who become excluded as a result of the loss of their health care license may never become eligible for reinstatement "even though the exclusion may no longer be necessary to protect patients or the programs."[28] OIG includes the example of a physician who was ineligible for reinstatement when a state medical board permanently revoked the physician's license. "This permanent ineligibility exists under current regulations even though another state or another licensing board subsequently granted the physician a license."[29] In addition, OIG notes that "we regularly are contacted by individuals who have changed professions and never intend to regain their original licenses but for whom the exclusion is a permanent obstacle to practicing a new health-care related profession."[30]

Unlike mandatory provisions which, absent aggravating circumstances, are subject to a five-year period of exclusion, many permissive exclusions result in permanent exclusions "even though the individuals were never charged with or convicted of criminal offenses."[31] Accordingly, OIG proposes to establish a process for early reinstatement which includes a list of factors OIG will consider in determining whether early reinstatement is appropriate.[32] The two subparts of the proposed section on early reinstatement will address two situations: (1) excluded individuals who request early reinstatement after fully and accurately disclosing the circumstances surrounding the underlying licensure action and establishing that they were permitted to retain a license in another jurisdiction or retain a different health care license in the same state; and (2) individuals who do not have valid health care licenses in another jurisdiction or another field but can demonstrate that they would no longer pose a threat to federal health care programs and beneficiaries.[33] OIG does not emphasize that there remains a "presumption against early reinstatement. . . . if the person has been excluded for less than 5 years."[34] The Proposed Rule is a far cry from simply running the exclusion concurrently with the license suspension and providing for automatic reinstatement once the licensure penalty has been served.

Long term care providers depend on licensed personnel regulated by an array of state licensure and disciplinary bodies. Many of the positions that the licensed personnel hold in long term care facilities turn over frequently. As a result, a constant stream of licensed professionals moves in and out of long term care facilities and moves from one long term care facility to another. At any given time, OIG has excluded many of these individuals because of license suspensions, some of which are based on relatively paltry accusations, such as the failure of the professional to notify the licensing authority of a new mailing address. The Proposed Rule retains service by mail as the sole mechanism OIG may utilize to notify providers of an exclusion,[35] an arguably insufficient mechanism to notify individuals already facing problems with mail notification.

Even if the excluded individual is aware of the exclusion, the individual is unlikely to report this condition to a prospective employer. Exclusions often appear months and years after the license suspension became effective—a situation not likely to improve in a system with no limitation on duration of time between the triggering event and the exclusion. Many of these employees or contractors have served their suspensions and are back in good standing with the licensure authorities before the application for new employment has been made. The prospective employer checks the employee's

licensure status and assumes all is well, not knowing that without warning the individual may pop up on the federal government's exclusion list long after employment has commenced.

OIG's solution for this problem is simply to recommend that providers conduct exclusion checks monthly,[36] when even weekly exclusion checks would still result in some excluded individuals remaining on a long term care provider's payroll for at least a few days. Large operators may have thousands of employees, and even smaller companies employ people by the hundreds. Slow growth in Medicare and deep cuts in state Medicaid programs do not make it easy for skilled nursing facilities (SNFs) to devote even greater resources to detecting minor and technical licensure issues resulting in exclusions.

Failure to Grant Immediate Access

OIG, like other federal agencies, may request paperwork from providers and others to assist in its investigations. The Proposed Rules now seek to clarify that providers and others must meet the OIG's access to such documents with more urgency than before. OIG proposes "technical changes" to the section regarding exclusion for failure to grant "immediate access."[37] OIG provides a definition for "failure to grant immediate access" as the "failure to produce or make available for inspection and copying the requested material upon reasonable request."[38]

> *Reasonable request* means a written request, signed by a designated representative of the OIG or MFCU [State Medicaid Fraud Control Unit] and made by a properly identified agent of the OIG or a MFCU during reasonable business hours, where there is information to suggest that the person has violated statutory or regulatory requirements under Titles V, XI, XVIII, XIX, or XX of the Act.[39]

From a reading of this proposed regulation, "reasonable request" simply means a request in writing, and the failure to provide the requested documentation within 24 hours (or sooner if OIG believes the material will be altered or destroyed) may result in exclusion.

In practical terms, this means that an SNF must drop whatever else it is doing to devote sufficient resources to respond to the OIG's or an MFCU's request for information, no matter how routine. Failure to comply, which may result in an exclusion, could be a virtual death sentence for most SNFs, which depend heavily on Medicare and Medicaid for their livelihood.

CMPs

In addition to the Proposed Rule on exclusion authority, OIG also issued the CMP Rule, which correlates to several proposed exclusion amendments resulting from the ACA. If the exclusion rules are the nails threatening long term care providers, CMP Rules are the hammer.[40] OIG originally developed the penalties for submitting claims by excluded providers to apply to providers who actually submitted claims.[41] In the long term care arena, a low-level licensed practical nurse (LPN) with a suspended license that OIG later excludes and an SNF unwittingly employs, does not submit claims. The SNF submits claims, but only in very small part on the basis of work performed by the one excluded LPN. The problem is compounded by the fact that many state licensing boards continue to renew the licenses of individuals known by the state and federal governments to be excluded and even, in some cases, directing those persons to find employment within the long term care profession as a condition of regaining a full license.

OIG commented in the May 12 proposed changes in the CMP Rule that "[d]ifficulties exist in determining the appropriate penalty and assessment amount for claims that are not separately billable by the excluded person."[42] Several state MFCUs resolved these difficulties by seeking to impose penalties on SNFs that unknowingly employed excluded persons based on the total amount of wages and benefits paid to the excluded individual during the period of the excluded individual's employment. OIG seeks to codify this approach in its Proposed Rules.[43]

One could argue that no SNF acting in a commercially reasonable manner would ever "knowingly" employ an excluded individual given the risk. However, many exclusion CMPs are based on the standard that the provider "should have known"[44] that the employee was excluded. Further, the mechanism for calculating damages payable by the SNF presupposes that the tainted employee performed services benefitting Medicare or Medicaid recipients and received payment for the commercially reasonable value of those services. Is it truly the purpose of Section 1128A(a)6 of the Social Security Act to capture "the value of the excluded person to the employing or contracting person"[45] absent any showing of harm to federal health care programs or beneficiaries of those programs?

Conclusion

Compliance with the exclusion and CMP Rules has become increasingly critical for long term care providers. No level of compliance, though, is entirely foolproof. Providers will be required to continue to devote substantial time and resources to protecting themselves from arguably technical violations of the law, resources which they could instead devote to patient care.

**The views expressed in this article are solely those of the authors and not those of Quarles & Brady LLP or any other individual or organization.*

1 Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities; Proposed Rule, 79 Fed. Reg. 26810 (May 9, 2014) (hereinafter Proposed Rule). The public comment period for this rule closed on July 8, 2014.
2 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).
3 Medicare Prescription Drug, Improvement Act of 2003, Pub. L. No. 103-173, 117 Stat. 2066 (2003).
4 Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules; Proposed Rule, 79 Fed. Reg. 27080 (May 12, 2014) (hereinafter CMP Rule). The public comment period for this rule closed on July 11, 2014.
5 Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 18, 2013) at 1-2 (hereinafter Special Advisory Bulletin).
6 Special Advisory Bulletin at 4; *see also* CMP Rule, 79 Fed. Reg. 27080, 27081 (May 12, 2014).
7 *Id.* at 4.
8 Section 1128(a) of the Social Security Act, 42 U.S.C. § 1320a-7(a).
9 Section 1128(b) of the Social Security Act, 42 U.S.C. § 1320a-7(b).
10 42 U.S.C. § 1320a-7(a)(1).
11 42 U.S.C. § 1320a-7(a)(2).
12 42 U.S.C. §§ 1320a-7(a)(3) -7(a)(4); 79 Fed. Reg. 26810, 26811 (May 9, 2014).
13 *Id.*
14 *Id.*
15 U.S. Department of Health & Human Services, Office of Inspector General, Semiannual Report to Congress, (April 2013 – September 2013), at i.
16 U.S. Department of Health & Human Services, Office of Inspector General, Semiannual Report to Congress, (October 1, 2013 – March 31, 2014), at ii.
17 79 Fed. Reg. 27080, 27080 (May 12, 2014).
18 *Id.* at 26811(*citing* § 6408(c) of the ACA). Section 6408(c) of the ACA expands OIG's exclusion authority by adding audit obstruction as a new basis for permissive exclusion. The ACA allows the OIG discretion to exclude a person for obstructing an audit in three areas: (1) where a person has been convicted of an offense in connection with the obstruction of an investigation or audit *related* to any criminal offense which would trigger mandatory exclusion; (2) under the permissive provision related to health care fraud or fraud in a governmental program; or (3) in situations where the investigation or audit relates to the direct or indirect receipt of federal health care program funds. 79 Fed. Reg. 26810, 26814 (May 9, 2014) (*citing* § 6408(c) of the ACA).
19 79 Fed. Reg. 26810, 26811 (*citing* § 6406(c) of the ACA). Section 6406(c) of the ACA expands OIG's exclusion authority to apply not only to those individuals and entities that furnish items or services for which payment may be made under Medicare or a state health care program, but also non-permissively to those individuals or entities that order such items, refer such items for furnishing, or certify the need for such items. 79 Fed. Reg. 26810, 26816 (May 9, 2014). In the Special Advisory Bulletin, OIG noted that this prohibition applies even when the federal payment itself is made to a state agency or a provider that is not excluded. OIG cautions in its Special Advisory Bulletin that "[t]o avoid liability, providers should ensure, at the point of service, that the ordering or prescribing physician is not excluded." Special Advisory Bulletin at 8.
20 79 Fed. Reg. 26810, 26811 (citing § 6402(d) of the ACA).
21 *Id.* at 26815.
22 *Id.* at 26815. OIG continues that in most cases, it "determines whether to seek an exclusion only when the settlement terms are set or there is a judgment" and that most FCA cases are resolved much later than six years after the underlying conduct.
23 *Id.* at 26816.
24 *Id.* at 26815.
25 *Id.* at 26815-26816.
26 *Id.* at 26810.
27 OIG claims that the proposed policy change removing the aggravating and mitigating factors is consistent with its current practice, that it "generally imposes exclusions under these sections [1128(b)(4) and (b)(5) of the Social Security Act] for the same period as that of the licensing board's or agency's action," and that the removal of the aggravating or mitigating factors would make the regulations consistent with OIG's general practice. "As a result, individuals are generally eligible for reinstatement once they regain their health care licenses or are allowed to participate in the Federal or State health care program." 79 Fed. Reg. 26810, 26814 (May 9, 2014).
28 *Id.*
29 *Id.*
30 *Id.*
31 *Id.* at 26815.
32 *Id.*
33 *Id.* Other proposed changes include a proposed increase of the financial loss aggravating factor to $15,000. *Id.* at 26813. The Proposed Rule also clarifies the circumstances surrounding the length of exclusion for an individual who has an ownership or control interest in a sanctioned entity, proposing that the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has or had the "prohibited relationship." *Id.* at 26816. Another proposed change provides for "testimonial subpoenas" pursuant to Section 6402(e) of the ACA. *Id.* at 26819.
34 79 Fed. Reg. 26810, 26823 (May 9, 2014).
35 *Id.* at 26818 ("In addition, consistent with longstanding practice, the OIG will continue to mail the notices of intent to exclude and all other notices relating to the imposition of exclusion via first-class mail.").
36 Special Advisory Bulletin, at 15. ("OIG updates the LEIE monthly, so screening employees and contractors each month best minimizes potential overpayment and CMP liability. Additionally, in January 2009, CMS issued a State Medicaid Director Letter (SMDL) recommending that States require providers to screen all employees and contractors monthly.").
37 79 Fed. Reg. 26810, 26816 (May 9, 2014).
38 *Id.* at 26824.
39 *Id.*
40 Sections 6402(d)(2)(A)(iii) and 6408(a) of the ACA amended the CMPL by adding new conduct that would subject a person to penalties, assessments, and/or exclusion from participation in the federal health care programs. The new covered conduct includes: (1) failure to grant OIG timely access to records, upon reasonable request; (2) ordering or prescribing while excluded when the excluded person knows or should know that a federal health care program may pay for the item or service; (3) making false statements, omissions, or misrepresentations in an enrollment or similar bid or application to participate in a federal health care program; (4) failure to report and return an overpayment that is known to the person; and (5) making or using a false record or statement material to a false or fraudulent claim. 79 Fed. Reg. 27080, 27081 (May 12, 2014) (*citing* the Social Security Act, at § 1128A(a)(8)– (12)). The proposed changes would be codified at 42 C.F.R. § 1003.200(b)(6)–(10), §1003.210(a)(6)–(9), and §1003.210(b)(3). *Id.*
41 *See generally*, Special Advisory Bulletin, at 4.
42 79 Fed. Reg. 27080, 27085 (May 12, 2014).
43 *Id.*
44 *Id.* at 27083-27084.
45 *Id.* at 27085.

Dealing with Known or Suspected Whistleblowers in Internal Investigations: Status of the Law, Challenges Facilities Face, and Strategies for Managing Risk

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Health care attorneys are frequently confronted with complaints from employees of long term care (LTC) and other post-acute health care providers who are currently, or who may one day become, whistleblowers (or qui tam relators) under the Federal False Claims Act (FCA or Law).[1] When faced with such allegations of noncompliant or fraudulent practices, health care attorneys, compliance officers, and providers often turn to internal compliance plans for guidance and may even initiate an internal investigation. Although most compliance plans likely provide a roadmap to regulatory compliance and set forth prudent policies and procedures to help direct an internal investigation, it is important to offer guidance on one of the most common questions associated with situations involving employee allegations of fraud: How should a health care provider deal with an employee who is a known or suspected whistleblower?

In addition to explaining the evolution of the FCA's anti-retaliation provision, this article aims to answer this difficult question and provide tips to help avoid liability under the FCA's anti-retaliation provision.

The FCA's Reliance on Qui Tam Relators and the Evolution of Whistleblower Empowerment

Referred to in its early years as "Lincoln's Law," U.S. Congress enacted the FCA in 1863 to recoup moneys paid on claims submitted to the federal government for faulty equipment delivered to the Northern troops during the Civil War.[2] The goal of the FCA has remained constant since its inception: Eradicate fraud against the government.[3] To accomplish this laudable goal, the FCA allows common citizens (referred to as "relators" or "whistleblowers") with knowledge of past or present fraud committed against the government to file qui tam lawsuits on behalf of the government.[4] Throughout the FCA's 150-year history, Congress has tempered relator incentives to file qui tam actions by increasing or decreasing pleading standards and by protecting relators from retaliation by employers.

The 1863 version of the FCA not only allowed relators to file qui tam lawsuits on behalf of the government, it also provided rich incentives for doing so.[5] The civil provisions of Lincoln's Law allowed a private citizen to bring a qui tam action on behalf of the federal government against anyone who knowingly submitted false claims for payment of federal funds.[6] If the qui tam lawsuit was successful, the offending party was required to pay double damages and a $2,000 penalty per false claim.[7] The relator, in turn, was entitled to receive 50% of the amount recovered.[8] The main problem with the 1863 version of the FCA was that the Law made it too easy for relators to file qui tam lawsuits. Because the original FCA did not require any independent knowledge of the alleged fraudulent conduct, relators soon learned that they could file qui tam actions based on information gleaned from government indictments and other publicly available information.[9]

Despite such rich incentives and minimal pleading standards, relators seldom used the original FCA for the first 60 years of the Law's existence. Once they discovered how easy it was to file a qui tam lawsuit, however, FCA litigation increased. By the early 1940s, relators were gleaning information from criminal FCA indictments of federal attorneys general to help craft civil qui tam complaints that were regularly devoid of any original information. A 1943 U.S. Supreme Court decision, *U.S. ex rel. Marcus v. Hess*[10]—and Congress' swift response to that decision—served as a death knell to what became known as the proliferation of "parasitic qui tam lawsuits."[11]

In *Marcus*, though critical of the practice, the Court held that based on a strict reading of the FCA relators were permitted to file qui tam lawsuits without offering any new information.[12] Congress read between the lines of the Court's decision in *Marcus*[13] and moved quickly to revise the FCA and alleviate the deluge of qui tam lawsuits that flooded the federal docket. The resulting legislation[14] barred qui tam suits based on information already within the government's possession.[15] Moreover, the 1943 amendments reduced relators' 50% share of recovery under Lincoln's Law to a mere 10% share if the government intervened in the qui tam action, and no more than 25% if the government declined to intervene.[16]

In 1986, the Senate again proposed to amend the FCA to encourage qui tam actions in an effort to combat the "rampant fraud in Government programs" that arose in the wake of the 1943 amendments.[17] At that time, the Senate Judiciary Committee estimated that instances of *unknown* fraud had likely drained as much as 1% to 10% of the entire federal budget, or $10 to $100 billion annually.[18] The fraud problem highlighted by the Senate Judiciary's Report required a significant departure from the post-1943 version of the FCA, and the final 1986 amendments delivered.

For starters, the 1986 amendments incentivized relators to file qui tam lawsuits by increasing the civil penalties to $5,000 to $10,000 per false claim and providing for treble rather than double damages.[19] The 1986 amendments also encouraged qui tam actions by increasing the relator's share of the recovery and providing protection from employer retaliation for blowing the whistle on FCA violations.[20] Codified at 31 U.S.C. § 3730(h), for the first time, the FCA's anti-retaliation provision provided a private right of action for any potential whistleblower employee who was discriminated against in any manner by an employer due to the employee's investigation or reporting of potential fraud.[21]

The 43 years of qui tam inactivity between the 1943 and 1986 amendments made it clear that the success of the FCA—and perhaps even the successful prevention of mass fraud against the federal government—depends on whistleblowers' ability to detect and report fraud. As one court noted, the 1986 amendments embraced this reality and empowered "a posse of ad hoc deputies to uncover and prosecute fraud against the government."[22]

Recent Amendments to the FCA's Whistleblower Anti-Retaliation Provision

In the two-plus decades that led up to the 2008 financial crisis, whistleblowers filed more than 6,000 qui tam lawsuits.[23] Despite the significant uptick in FCA recoveries, Congress enacted a series of amendments in 2009 and 2010 to set aside judicial decisions it felt did not coincide with the

intent of the FCA and to further empower whistleblowers to protect the "extraordinary economic support" the government was preparing to pump into the economy.[24] The Fraud Enforcement and Recovery Act of 2009[25] (FERA) and the Dodd-Frank Wall Street Reform and Consumer Protection Act[26] (Dodd-Frank) contained two such amendments.

FERA, signed into law on May 20, 2009, expanded the FCA's anti-retaliation provision to proscribe retaliation against "contractors and agents" in addition to employees. Interestingly, FERA also narrowed the FCA's anti-retaliation provision by redefining "protected conduct" (i.e., conduct immune from retaliation under the FCA) as "lawful acts done . . . in furtherance of other efforts to stop 1 or more [FCA] violations," thereby protecting only conduct that involved attempts to stop alleged fraud. Only 13 months later, however, Dodd-Frank again revised the definition of "protected conduct" to include "lawful acts done . . . in furtherance of [an FCA action] or other efforts to stop 1 or more violations."[27]

Together, the FERA and Dodd-Frank amendments to the FCA provide unprecedented levels of protection from employer retaliation to known and suspected FCA whistleblowers. To sidestep avoidable pitfalls associated with whistleblower retaliation lawsuits, health care providers, attorneys, and compliance officers should take time to understand the text and judicial interpretations of Section 3730(h).

Elements of an FCA Retaliation Claim

To prevail in an FCA whistleblower retaliation claim, an employee, contractor, or agent must demonstrate three elements: (1) the whistleblower was engaged in protected conduct; (2) the defendant knew that the whistleblower was engaged in protected conduct; and (3) the defendant made an adverse employment decision because of the whistleblower's protected conduct.[28]

"Protected Conduct" Under the FCA

A person engaged in conduct protected by the FCA "must be investigating matters which are calculated, or reasonably could lead to a viable FCA action."[29] The employee does not have to actually file a qui tam action to engage in "protected conduct." In fact, the employee does not even have to know the FCA exists; rather, the employee must demonstrate only a reasonable belief that the employer was committing an act of fraud against the government that would be actionable under the FCA and that the employee made an effort to investigate or prevent such fraud.[30]

Defendant's Knowledge of Protected Conduct

A whistleblower must show that "the employer had knowledge the employee engaged in 'protected activity.'"[31] Here, too, courts apply a reasonableness standard and require that the employee's words or actions put the employer on notice that FCA litigation is a "reasonable possibility."[32] In applying this standard, courts have held that mere grumblings or complaints about regulatory noncompliance are insufficient to inform an employer that an employee is engaged in protected conduct under the FCA.[33] Courts also place a considerable amount of weight on the employee's job description. For example, some courts have required "fraud alert employees" (i.e., employees whose job descriptions include reporting on and/or investigating regulatory compliance) to provide explicit notice that their conduct is motivated by the intent to file a qui tam lawsuit.[34] At the very least, courts may require that such fraud alert employees use certain "buzz words" such as "fraudulent"[35] or "illegal"[36] when voicing concerns to employers.

Causal Connection Between Protected Conduct and Adverse Employment Action

After demonstrating that the employer knew the employee was engaged in protected conduct, a whistleblower also must "supply sufficient facts from which a reasonable jury could conclude that the employee was discharged because [the employee was engaged in the protected conduct]."[37] There also must be "temporal proximity" (defined as being "very close") between the time the employer learned the employee was engaged in protected conduct and the time of the adverse employment action.[38] However, even if an employee demonstrates all three elements and temporal proximity exists, an employer can still defeat an FCA retaliation claim by demonstrating that the adverse employment action would have occurred even if the employee had not engaged in the protected conduct.[39]

Tips to Avoid Liability Under the FCA's Retaliation Provision

Implement a Robust Compliance Program

LTC and other post-acute health care providers should develop and implement a comprehensive compliance program in an effort to prevent retaliation against known or suspected whistleblowers and to prevent potential FCA retaliation claims by relators. Often, employees become whistleblowers when they feel that the organization has failed to adequately address their concerns internally or if they are hesitant to disclose concerns directly for fear of repercussions. To encourage employees to voice concerns as soon as possible and to ensure that organizations adequately address all concerns, health care providers should formulate a compliance program that does all of the following:

- Ensures that compliance is a priority that is taken seriously and that all employees are aware of their organization's compliance guidelines;
- Provides resources for employees to report concerns internally within the organization, including a hotline to report anonymously;
- Appoints a compliance officer to oversee compliance throughout the organization and to whom employees can report actual or suspected wrongdoing;
- Performs corporate compliance training periodically. Stresses employees' integral role in ensuring that the organization acts lawfully. Encourages employees to bring any concerns to the forefront immediately so the organization can address and remedy any potential compliance concerns or breaches;
- Develops a non-retaliation policy and ensures understanding of the policy by all employees, specifically supervisors;
- Retains outside counsel in the event of a compliance violation or suspected violation to perform an independent investigation; and
- Conducts exit interviews of employees and asks questions specific to the organization's commitment to compliance to determine whether compliance systems and processes are operating effectively.

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Take Extra Time to Plan and Conduct Compliance Investigations Involving a Known or Suspected Whistleblower

Once actual or suspected fraud or wrongdoing is reported, the health care provider should retain outside counsel immediately to conduct an investigation and to preserve privilege over that investigation. Although some investigations stem from anonymous complaints while others feature employees who come forward directly with their concerns, the organization and investigating counsel should always operate under the assumption that any employee may be a potential or actual whistleblower. While conducting a compliance investigation, the organization should take into account the following recommendations:

- Ensure immediate initiation of the compliance investigation upon learning of a suspected or actual violation. Not only is it critical to detect, report, and correct any actual violations immediately under the FCA, it is important for potential whistleblowers to know that the organization has heard their concerns and takes them seriously;
- During the course of the investigation, reiterate that the organization takes compliance concerns very seriously and that it appreciates employees coming forward. Recruit reinforcement of supervisors or regional or divisional supervisors to meet with employees and show support;
- Stress the organization's non-retaliation policy and ensure that the policy is followed. Retaliation is illegal pursuant to the FCA, and an organization's compliance program should expressly prohibit it. Reporting a suspected or actual violation must not affect an employee's job in any way, including termination, change in hours, change in job responsibilities, threats, harassment, or discrimination of any kind;
- Correct any messaging problems immediately. Compliance investigations may reveal that no wrongdoing actually occurred but that employees feel pressure to hit certain targets for the financial benefit of the organization. Train supervisors on how to properly message employees and on the risks involved when the focus becomes financial instead of patient-centered; and
- If the known or potential whistleblower resigns after reporting a suspected or actual violation, attempt to conduct an exit interview to give the employee the chance to air all complaints. If the employee becomes a whistleblower, the exit interview can assist in establishing that the organization investigated all complaints brought to its attention.

The Special Case of the Compliance Investigation that Reveals Potential Whistleblower Wrongdoing

An investigation may reveal that the potential whistleblower committed the underlying fraud or wrongdoing. In such a situation, the organization must take steps to protect itself but should use caution prior to taking adverse employment action:

- Conduct a thorough investigation of the employee's potential wrongdoing and obtain verifiable facts and documents to support the adverse action;
- Confront the employee about the fraud or wrongdoing, and afford the employee an opportunity to explain his actions. Maintain the attorney-client privilege by ensuring that outside legal counsel is present during this conversation; and
- With the consultation of legal counsel, ensure that fraudulent conduct is disclosed and notify the appropriate agencies of the employee's conduct.

Conclusion

LTC providers, like the rest of the modern health care industry, must comply with complex and constantly evolving federal laws and regulations governing the provision of care and how claims for payment must be submitted. The task of complying with these rules and regulations can become even more difficult when and if a provider's employee investigates alleged noncompliance. LTC providers must recognize the risks associated with retaliating against a potential or known whistleblower and implement policies and procedures now to mitigate such risks in the future.

1 The FCA is codified at 31 U.S.C. §§ 3729-3733.
2 United States Department of Justice (DOJ) Pub., The False Claims Act: A Primer, *available at:* www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Primer.pdf (last visited August 5, 2014).
3 S. REP. No. 99-345, at 8 (1986).
4 31 U.S.C. § 3730.
5 S. REP. No. 99-345, at 10 (1986).
6 *Id.*
7 *Id.*
8 *Id.*
9 *Id.* at 544.
10 *Id.*
11 H. Rept. No. 78-263 at 2 (1943).
12 *Marcus* 317 U.S. 547.
13 *Id.* at 548, n. 9 ("There is of course no reason why Congress could not, if it had chosen to do so, have provided specifically for the amount of new information which the informer must produce to be entitled to reward.")
14 Pub. L. No. 78-213, 57 Stat. 608 (1943).
15 31 U.S.C. 232(C) (1946).
16 57 Stat. at 609; *compare*, 31 U.S.C. § 234 (1940), *with* 31 U.S.C. § 232(E) (1946).
17 S. REP. No. 99-345, at 13 (1986).
18 *Id.*
19 *Id.* at 17.
20 *Id.* at 34.
21 *Id.*
22 *U.S. ex rel. Milam v. Univ. of Tex. M.D. Anderson Cancer Center,* 961 F.2d 46, 49 (4th Cir. 1992).
23 DOJ Pub. FRAUD STATISTICS OVERVIEW October 1, 1986 - September 30, 2008 Civil Division (Nov. 2008) *available at:* www.justice.gov/opa/pr/2008/November/fraud-statistics1986-2008.htm.
24 S. REP. No. 111-10 at 4 (2009), *as reprinted in* 2009 U.S.C.C.A.N. 430, 432.
25 FERA Pub. L. No. 111-21, 123 Stat 1617 (2009).
26 Dodd-Frank Pub. L. No. 111-203, 124 Stat 1376 (2010).
27 31 U.S.C. 3730(h).
28 *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996). Note that the 8th Circuit also requires a whistleblower to prove that the whistleblower's protected conduct solely motivated the retaliation. *See Schuhardt v. Washington Univ.*, 390 F.3d 563, 566 (8th Cir. 2004).
29 *Id.*
30 *Fanslow v. Chicago Mfg. Ctr., Inc.*, 384 F.3d 469, 480 (7th Cir. 2004) (protected conduct only occurs when the employee had reasonable, good-faith belief that the employer is committing fraud against the United States); *see also Weihua Huang v. Rector and Visitors of U. of Va.*, 896 F. Supp. 2d 524, 551 (W.D. Va. 2012) ("the question is not whether, looking backward, Defendants' conduct was actionable under the FCA, but rather whether, at the time, [the Plaintiff] believed his disclosure could reasonably lead to an FCA action").
31 S. REP. No. 99-345, at 35 (1986).
32 *U.S. ex rel. Alpharma, Inc.*, 493 Fed.Appx. 380, 388 (4th Cir. 2012).
33 *Campion v. Northeast Utils.*, 598 F. Supp. 2d 638, 657-658 (M.D. Pa. 2009).
34 *Id.; see also U.S. ex rel. Herron v. Indianapolis Neurosurgical Grp.*, 2013 WL 652538 *8-9 (S.D. Ind. Feb. 21, 2013).
35 *U.S. ex rel. Sharp v. E. Okla. Orthopedic Ctr.*, 2009 WL 499375, *26 (N.D. Okla. Feb. 27, 2009).
36 *U.S. ex rel. Marlar v. BWXT Y-12, LLC*, 525 F.3d 439, 449-450 (6th Cir. 2008).
37 *Luckey v. Baxter Health care Corp.*, 2 F. Supp. 2d 1034, 1065 (N.D. Ill 1998).
38 *Shenoy v. Charolette-Mecklenburg Hosp. Auth.*, 521 Fed.Appx. 168, 175 (4th Cir. 2013) (unpublished), *citing Clark County Sch. Dist. v. Breeden*, 532 U.S. 268, 273 (2001) ("The timing between an employer's knowledge of protected activity and an adverse employment action. . . must be very close").
39 *U.S. ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 479 (5th Cir. 2012).

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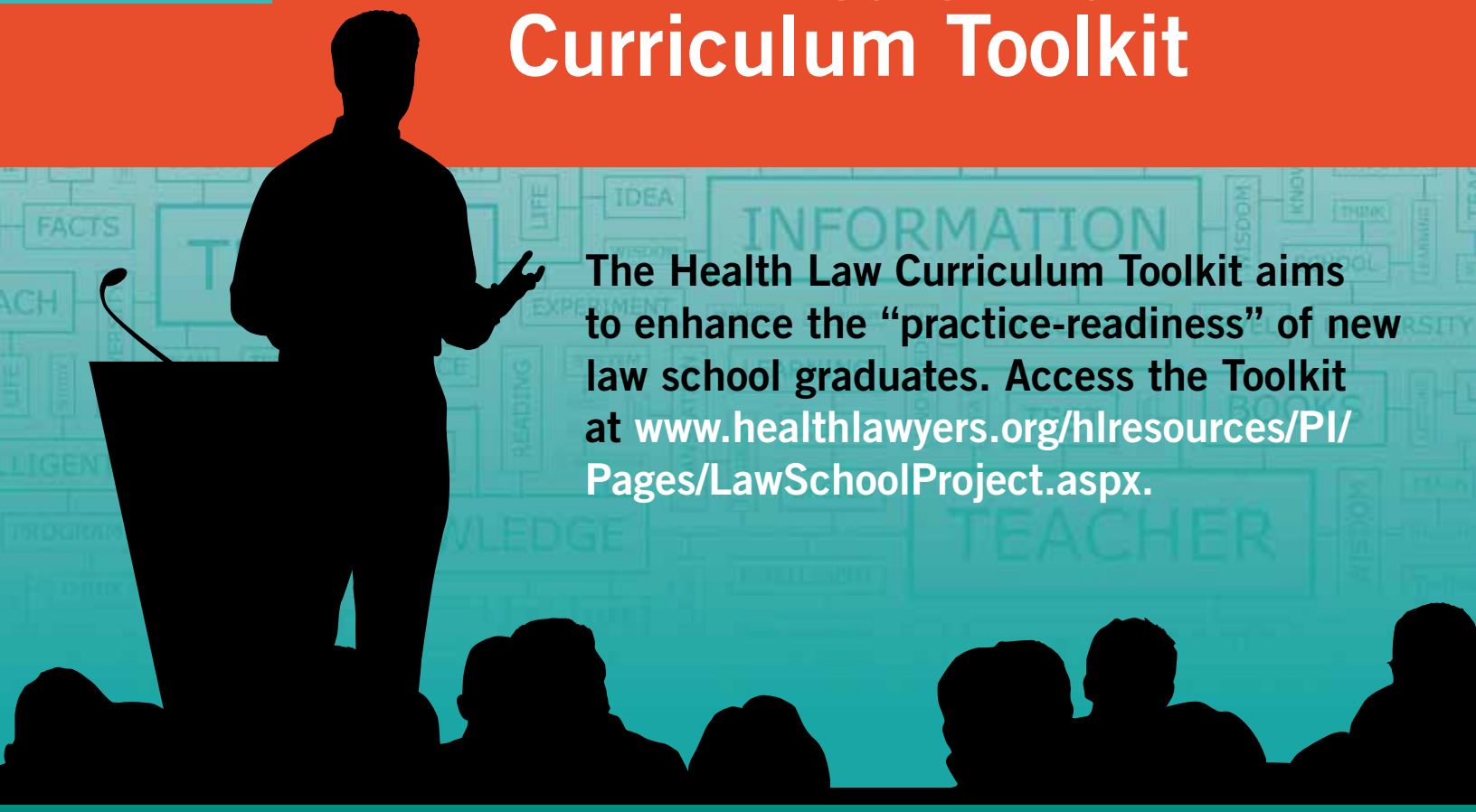

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