

# Journal of Health Care Law and Policy

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Volume 15 | Issue 2

Article 2

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### Recommended Citation

Daniel R. Levinson, *A New Era of Medicare Oversight*, 15 J. Health Care L. & Pol'y 249 (2012).  
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# A NEW ERA OF MEDICARE OVERSIGHT

DANIEL R. LEVINSON\*

Medicare constitutes the largest health insurance program in the nation,<sup>1</sup> and as the health care landscape changes, so does Medicare. In its early decades, Medicare focused on “paying the bill” for beneficiaries’ hospital and doctor visits. Starting in the 1970s, the program was run by an agency with a name that reflected this reimbursement orientation: the Health Care Financing Administration. In the new millennium, Medicare’s administering agency was renamed the Centers for Medicare and Medicaid Services (“CMS”),<sup>2</sup> reflecting a shift toward broader engagement in the administration of the health care programs. This shift set the stage for more dramatic changes in the Medicare program aimed at improving care and lowering costs through value-driven delivery and payment reforms.

Similar changes have been happening across health care, fueled by innovations in science and information technology, advances in evidence-based medicine and quality measurement, and the urgent need to address health care spending. These changes, and the extraordinary pace at which they are unfolding, have important implications for Medicare and other Federal health care programs.

Evidence of these changes can be seen in the emergence of integrated and coordinated models for delivering health care services to patients in both the public<sup>3</sup> and private sectors.<sup>4</sup> The premise of these models is that health care

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1. OFFICE OF RESEARCH, EVALUATION, AND STATISTICS, SOCIAL SECURITY ADMINISTRATION, ANNUAL STATISTICAL SUPPLEMENT TO THE SOCIAL SECURITY BULLETIN, 2011 44 (Feb. 2012), available at <http://www.ssa.gov/policy/docs/statcomps/supplement/2011/supplement11.pdf>.

2. CMS administers both the Medicare and Medicaid programs. *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov> (last visited June 7, 2012). The principles set forth in this article are also applicable to the administration of the Medicaid program.

3. For example, the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2011) (codified as amended in scattered sections of 26 U.S.C. and 42 U.S.C.), *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 [hereinafter Affordable Care Act], included significant provisions aimed at improving quality and reducing costs in the Medicare and Medicaid programs through delivery and payment reforms, including, for example, accountable care organizations, medical homes, bundled payments, value-based purchasing, and various demonstration programs. *See generally* Affordable Care Act, Title III. *See also, e.g.*, Lyle Nelson, *Lessons from Medicare’s Demonstration Projects on Disease Management and Care Coordination* 3

providers can achieve improved results in health outcomes and efficiencies at reduced costs by coordinating patient care across providers, enhancing chronic disease management,<sup>5</sup> eliminating unnecessary duplication of tests and services, reducing unnecessary hospital readmissions, adopting electronic health records, increasing the rate of preventive care and wellness services, promoting patient

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(Health & Human Res. Div., Cong. Budget Office, Working Paper 2012-01, 2012) (describing Medicare demonstration programs); CTRS. FOR MEDICARE & MEDICAID SERVS., ROADMAP FOR IMPLEMENTING VALUE DRIVEN HEALTHCARE IN THE TRADITIONAL MEDICARE FEE-FOR-SERVICE PROGRAM 3, [https://www.cms.gov/QualityInitiativesGenInfo/downloads/VBPRoadmap\\_OEA\\_1-16\\_508.pdf](https://www.cms.gov/QualityInitiativesGenInfo/downloads/VBPRoadmap_OEA_1-16_508.pdf) (last visited Mar. 30, 2012) (describing various Medicare payment initiatives). States are also developing new models for the Medicaid program. See, e.g., *State Demonstrations*, CTRS. MEDICARE & MEDICAID SERVS., U.S. DEP'T HEALTH AND HUMAN SERVS. (last visited Feb. 9, 2012), <http://innovations.cms.gov/initiatives/State-Demonstrations/index.html> (describing demonstration programs in 15 states to better coordinate care for individuals dually eligible for both Medicaid and Medicare); KITTY PURINGTON ET AL., NAT'L ACAD. FOR STATE HEALTH POL'Y, THE COMMONWEALTH FUND, ON THE ROAD TO BETTER VALUE: STATE ROLES IN PROMOTING ACCOUNTABLE CARE ORGANIZATIONS 14 (2011), available at [http://www.commonwealthfund.org/-/media/Files/Publications/Fund%20Report/2011/Feb/On%20the%20Road%20to%20Better%20Value/1479\\_Purington\\_on\\_the\\_road\\_to\\_better\\_value\\_ACOs\\_FINAL.pdf](http://www.commonwealthfund.org/-/media/Files/Publications/Fund%20Report/2011/Feb/On%20the%20Road%20to%20Better%20Value/1479_Purington_on_the_road_to_better_value_ACOs_FINAL.pdf) (describing various state efforts to promote quality care and efficiency). As this article goes to press, a decision regarding the constitutionality of the Affordable Care Act is pending from the Supreme Court of the United States. See generally *Patient Protection and Affordable Care Act Cases*, SUPREME COURT OF THE U.S., <http://www.supremecourt.gov/docket/PPAACAspx> (last updated Mar. 26, 2012) (providing information on the six consolidated cases). However, concepts of integration, coordination, and value in health care payment and delivery, manifested in the Affordable Care Act, preceded the legislation, and it is posited here that these concepts—and the corresponding need for effective approaches to oversight—will continue to develop in public and private health insurance programs regardless of the outcome of the Supreme Court's decision.

4. The private sector is increasingly experimenting with accountable care organizations and other performance based models. See generally, e.g., Robert A. Berenson & Rachel A. Burton, *Accountable Care Organizations in Medicare and the Private Sector: A Status Update*, TIMELY ANALYSIS OF IMMEDIATE HEALTH POL'Y ISSUES (Urban Inst., Washington, D.C.), Nov. 2011, at 3–4 (describing private sector initiatives); Jonathan Block, *Success of Blues Plans' Medical Homes Initiative Prompts Growth*, HEALTH BUS. DAILY (Nov. 7, 2011), <http://aishealth.com/archive/nhpw102411-05> (describing private insurer medical home projects); Susan DeVore & R. Wesley Champion, *Driving Population Health through Accountable Care Organizations*, 30 HEALTH AFF. 41, 42 (2011) (describing a private sector accountable care initiative); Aparna Higgins et al., *Early Lessons from Accountable Care Models in the Private Sector: Partnerships Between Health Plans and Providers*, 30 HEALTH AFF. 1718, 1718 (2011) (highlighting the development of collaborative health care models in the private sector); Robert E. Mechanic et al., *Medical Group Responses to Global Payment: Early Lessons from the 'Alternative Quality Contract' in Massachusetts*, 30 HEALTH AFF. 1734, 1734 (2011) (describing a private insurer program in Massachusetts involving global payments and quality bonuses); ARICCA D. VAN CITTERS ET AL., THE COMMONWEALTH FUND, FOUR HEALTH CARE ORGANIZATIONS' EFFORTS TO IMPROVE PATIENT CARE AND REDUCE COSTS 1–2 (2012) (case studies of four health systems participating in a private sector accountable care initiative). Notably, almost all private and employee health insurance plans offer disease management and care coordination programs. See Nelson, *supra* note 3, at 2.

5. A relatively small portion of the Medicare population accounts for the majority of Medicare fee-for-service spending. See, e.g., HENRY J. KAISER FAMILY FOUND., MEDICARE POLICY FACTSHEET: MEDICARE SPENDING AND FINANCING (2011) (noting that in 2007, ten percent of beneficiaries accounted for approximately fifty-nine percent of all Medicare fee-for-service spending). Focusing care improvement activities on addressing the needs and health of the most expensive patient populations offers the potential for meaningful savings.

engagement in care, and redesigning care processes to improve quality. Payment incentives for providers under such models are designed to support the transition to coordinated care and reward the accomplishment of better care for beneficiaries at reduced costs. A recent example of this approach is the Medicare Shared Savings Program (“SSP”) established under the Affordable Care Act, which introduced accountable care organizations (“ACOs”)<sup>6</sup> into the Medicare program to manage and coordinate care for fee-for-service beneficiaries.<sup>7</sup>

Oversight of the Medicare program will need to adapt to this changing dynamic. The Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) seeks to detect and prevent fraud and abuse, as well as promote the economy, efficiency, and effectiveness of HHS programs.<sup>8</sup> This mission is a responsibility shared with program officials and law enforcement authorities throughout government.<sup>9</sup> The challenge is to adopt oversight approaches that are suited to an increasingly complex and sophisticated health care system and tailored to protect programs and patients from existing and new vulnerabilities. The government and private sector stakeholders must capitalize on new tools and capabilities for detecting problems, including better health information technology that facilitates smarter, timelier data collection and analysis. The scope and execution of the oversight mission—from prevention efforts to enforcement—must be adaptable, nimble, and responsive to change. OIG itself is continually focused on improving internal coordination among multiple disciplines to optimize its impact and value.<sup>10</sup>

In the context of coordinated care and other value-driven programs, the oversight mission can be accomplished most effectively through a strategy that combines five discrete, but connected, areas into an integrated approach to program protection: program gatekeeping, sound payment, program compliance, effective monitoring, and government remediation.<sup>11</sup>

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6. The term “ACO” is used in this essay to refer specifically to ACOs under the SSP; however, accountable care organizations, more generally, exist in other settings.

7. Affordable Care Act, § 3022 (current version at 42 U.S.C. § 1395jjj(a)(1)). *See also Accountable Care Organizations*, OFFICE INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp> (last visited Mar. 27, 2012).

8. Inspector General Act of 1978, 5 U.S.C. app. 3 § 2(1)–(2) (2006). HHS OIG oversees all HHS programs, including, for example, Medicare, Medicaid, the Public Health Service, and others. *See About Us*, OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., <http://oig.hhs.gov/about-oig/about-us/index.asp> (last visited Mar. 26, 2012); *See generally OIG at HHS*, TWITTER, <http://twitter.com/OIGatHHS> (last visited Mar. 26, 2012) (providing updates of OIG activities).

9. *See* 5 U.S.C. app. 3 § 4(4) (2006) (noting that the Inspector General works with “other Federal agencies, State and local governmental agencies, and nongovernmental entities”).

10. Within OIG, the mission is carried out by auditors, evaluators, investigators, attorneys, and management and support staff. *See generally*, e.g., OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., WORK PLAN: FISCAL YEAR 2012 ii (2012) (describing OIG’s components).

11. These principles are not new; they draw on earlier OIG work that identified five principles of an effective program integrity strategy, including scrutinizing prospective providers prior to their enrollment in health care programs; establishing payment methodologies that are reasonable and

## I. PROGRAM GATEKEEPING

If providers do not meet the standards of professionalism and financial trustworthiness, a program's financial integrity and patients' safety may be compromised. Just as one of the best ways to keep thieves out of one's home is to lock the front door, one of the best ways to keep dishonest providers out of a health care program is to control entry into the program.

Gatekeeping has been a program challenge since the very beginning.<sup>12</sup> Historically, Medicare enrolled "any willing provider" in the interest of ensuring access to care for beneficiaries.<sup>13</sup> This orientation, stemming from a concern about beneficiary access, created fraud and abuse vulnerabilities that were further compounded by Medicare's mandate to make payments promptly.<sup>14</sup> From an integrity standpoint, this expedited turnaround in reimbursement complicates the ability to stop or recover inappropriate payments, leading to a "pay and chase"<sup>15</sup> enforcement environment and a greater likelihood that the government may not be made whole for erroneous or fraudulent claims.

There are promising developments, however, in the effort to better police enrollment and prevent unscrupulous entities and individuals masquerading as legitimate health care providers from gaining entry to the program and billing for unnecessary or phantom services. The Medicare program and law enforcement are advancing access to "real time" and integrated data, and implementing more sophisticated data analytics to prevent payment for illegitimate claims and to identify suspected fraud more quickly.<sup>16</sup> Medicare is suspending payments to

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responsive to changes in the marketplace; assisting the regulated community in adopting practices that promote compliance with program requirements; vigilantly monitoring programs for evidence of fraud, waste, and abuse; and swiftly responding to detected problems. *See, e.g., Cutting Waste, Fraud, and Abuse in Medicare and Medicaid: Hearing Before the Subcomm. on Health Before the H. Comm. on Energy and Commerce*, 111th Cong. 3 (2010) (statement of Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., U.S. Dep't of Health & Human Servs.).

12. *See generally A Perspective on Fraud, Waste, and Abuse Within the Medicare and Medicaid Programs: Hearing Before the Subcomm. on Health of the H. Comm. on Oversight and Gov't Reform*, 112th Cong. 7 (2011) (statement by Gerald T. Roy, Deputy Inspector Gen. for Investigations, Office of Inspector Gen., U.S. Dep't of Health & Human Servs.) ("The Department has faced challenges in ensuring the integrity of the program's provider and supplier enrollment processes."). *See also OFFICE INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., SOUTH FLORIDA SUPPLIERS' COMPLIANCE WITH MEDICARE STANDARDS: RESULTS FROM UNANNOUNCED VISITS* 3, 4, 10 (2007) (identifying vulnerabilities in the DMEPOS supplier enrollment process and providing recommendations for strengthening the system).

13. *See generally A Perspective on Fraud, Waste, and Abuse Within the Medicare and Medicaid Programs*, *supra* note 12, at 7 (statement of Gerald T. Roy) ("Since its inception, Medicare has been a program that allows 'any willing provider' to provide services for beneficiaries.").

14. *See, e.g.*, 42 U.S.C. §§ 1395h(c), 1395u(c) (2010) (establishing payment requirements).

15. "Pay and chase," as used in this essay, refers to reliance on after-the-fact enforcement to recoup improperly claimed or stolen funds.

16. *See generally Harnessing Technology and Innovation to Cut Waste and Curb Fraud in Federal Health Programs: Hearing Before the Subcomm. on Fed. Fin. Mgmt., Gov't Info., Fed. Servs., and Int'l Sec., S. Comm. on Homeland Sec. & Gov't Affairs*, 112th Cong. (2011) (statement of Lewis Morris,

providers suspected of fraud and using pre-payment review to help move from “pay and chase” to prevention.<sup>17</sup> OIG and Federal and State investigators and prosecutors launched a Strike Force in South Florida in 2007 to pursue durable medical equipment suppliers and infusion clinics suspected of Medicare fraud using new techniques.<sup>18</sup> The Strike Force Model was expanded in 2009 under a national initiative, the Health Care Fraud Prevention and Enforcement Action Team (“HEAT”) initiative.<sup>19</sup> Working in nine metropolitan areas<sup>20</sup> across the nation, from Brooklyn to Los Angeles, the Medicare Fraud Strike Force teams have charged more than 1150 defendants who collectively billed the Medicare program more than \$2.9 billion.<sup>21</sup> Many of the targets of the original Strike Forces were sham providers that enrolled not to provide services, but solely to scam the system.<sup>22</sup>

Strike Force and other law enforcement work demonstrate the need for better upfront prevention by the Medicare program. The effort to ensure that only legitimate providers can bill Medicare was bolstered by Title VI of the Affordable Care Act, which authorized additional funding for anti-fraud activities and strengthened Medicare’s pre-enrollment systems to better identify providers that either do not meet Medicare standards or present a heightened risk of fraud.

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Chief Counsel, Office of Inspector Gen., U.S. Dep’t of Health & Human Servs.), available at [http://oig.hhs.gov/testimony/docs/2011/morris\\_testimony\\_07122011.pdf](http://oig.hhs.gov/testimony/docs/2011/morris_testimony_07122011.pdf) (describing government uses of technology to address program integrity); *Reducing Fraud, Waste, and Abuse in Medicare: Hearing Before the Subcomms. on Health & Oversight and the H. Comm. on Ways and Means*, 111th Cong. 4 (2010) (statement by Lewis Morris, Chief Counsel, Office of Inspector Gen., U.S. Dep’t of Health & Human Servs.), [http://oig.hhs.gov/testimony/docs/2010/morris\\_testimony61410.pdf](http://oig.hhs.gov/testimony/docs/2010/morris_testimony61410.pdf).

17. See *Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges: Hearing Before the S. Comm. on Fin.*, 112th Cong. 6 (2011) (statement of Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., U.S. Dep’t of Health & Human Servs.), available at [http://oig.hhs.gov/testimony/docs/2011/levinson\\_testimony\\_03022011.pdf](http://oig.hhs.gov/testimony/docs/2011/levinson_testimony_03022011.pdf).

18. See *Improving Efforts to Combat Health Care Fraud: Hearing Before the Subcomm. on Oversight, H. Comm. on Ways and Means*, 112th Cong. 4 (2011) (statement of Lewis Morris, Chief Counsel, Office of Inspector Gen., U.S. Dep’t of Health & Human Servs.), available at [http://oig.hhs.gov/testimony/docs/2011/morris\\_testimony\\_03022011.pdf](http://oig.hhs.gov/testimony/docs/2011/morris_testimony_03022011.pdf).

19. HEAT was launched by HHS Secretary Kathleen Sebelius and Attorney General Eric Holder in May 2009 with the goal of increasing cooperation between HHS and DOJ in combating health care fraud. See Press Release, U.S. Dep’t of Health & Human Servs., Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention and Enforcement Action Team (May 20, 2009), <http://www.hhs.gov/news/press/2009pres/05/20090520a.html>; *HEAT Task Force Success: Health Care Fraud Prevention and Enforcement Action Team (HEAT)*, STOPMEDICAREFRAUD.GOV, <http://stopmedicarefraud.gov/heattaskforce/index.html> (last visited March 20, 2012).

20. U.S. DEP’T OF HEALTH & HUMAN SERVS. & DEP’T OF JUSTICE, *HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2011 10–11* (2012) [hereinafter 2011 ANNUAL REPORT]. Strike Forces are concentrated in geographic locations identified as prevalent for Medicare fraud. See, e.g., *A Perspective on Fraud, Waste, and Abuse Within the Medicare and Medicaid Programs*, *supra* note 12, at 10 (statement of Gerald T. Roy).

21. See 2011 ANNUAL REPORT, *supra* note 20, at 11.

22. See, e.g., *A Perspective on Fraud, Waste, and Abuse Within the Medicare and Medicaid Programs*, *supra* note 12, at 3–4 (statement of Gerald T. Roy) (describing ways in which health care providers scam Medicare and Medicaid).

Continuing the promising movement away from a “pay and chase” environment requires attention to gatekeeping in new Medicare programs. This may entail using methods other than the ordinary enrollment processes in order to evaluate new entities, such as coordinated care entities, that may not be enrolling as traditional providers. For example, in the SSP regulations, CMS identified program integrity history among characteristics to be considered in evaluating program applicants.<sup>23</sup> Such measures can help provide the government and the public with greater confidence that participating providers and other entities are trustworthy.

## II. SOUND PAYMENT

Sound payment policy and practices are essential to protecting the Federal fisc.<sup>24</sup> Three aspects are of particular importance: design, implementation, and monitoring. Payment models must be designed to achieve intended outcomes, payment rates and amounts must be established correctly, and the actual payments made must be examined to ensure that they are proper. Past OIG experience examining Medicare program payments has identified challenges in these areas.<sup>25</sup> Misalignment is one such challenge and can result from a variety of factors. For example, misalignments can arise when a payment design is not updated to reflect changes in medical or business practices or program goals.<sup>26</sup> Payment design can

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23. Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,981 (Nov. 2, 2011) (to be codified at 42 C.F.R. § 425.304(b)).

24. Based on actuarial projections from the Office of the Actuary for CMS, in FY2012, government health care spending is projected to be approximately forty-six percent of national health spending, and the Federal government is expected to cover approximately sixty-one percent of that amount. See OFFICE OF THE ACTUARY, CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURE PROJECTIONS 2011-2021 22, available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2011PDF.pdf>. By FY2021, government health care spending is projected to grow to approximately fifty percent of the national amount, and the Federal government portion will grow too, up to approximately two-thirds of total government health spending. *Id.*; Sean P. Keehan et al., *National Health Expenditure Projections: Modest Annual Growth Until Coverage Expands and Economic Growth Accelerates*, 31 HEALTH AFF. (forthcoming 2012), available at <http://content.healthaffairs.org/content/early/2012/06/11/hlthaff.2012.0404.full>. Sound payment policies and practices also protect beneficiaries, who often pay a portion of the bill for many services. *See, e.g.*, 42 U.S.C. § 1395e (2006) (Medicare Part A deductibles and coinsurance).

25. *See generally* OFFICE OF INSPECTOR GEN., FY 2010 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY OFFICE OF INSPECTOR GENERAL III-4 through 10 (2010) (describing some of the challenges and approaches taken to address them).

26. OIG’s work examining Medicare payment for global surgery fees is instructive on this point. OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., A-05-07-00077, NATIONWIDE REVIEW OF EVALUATION AND MANAGEMENT SERVICES INCLUDED IN EYE AND OCULAR ADNEXA GLOBAL SURGERY FEES FOR CALENDAR YEAR 2005 1 (2009), available at <http://oig.hhs.gov/oas/reports/region5/50700077.pdf>. Medicare bundles payments for certain surgeries and associated services into “global surgery fees.” *Id.* However, medical practice has evolved since the global fees were designed. *Id.* at 3-4. In the case of eye surgeries, for example, physicians typically provide fewer services than is assumed in the payment model. *Id.* at 3. OIG determined that payment rates have not been adjusted accordingly, resulting in payment inefficiencies. *Id.* at 5.

also impact how care is delivered. The effects of payment structures on practice should be monitored to guard against unintended consequences for quality or cost. Appropriate safeguards and monitoring are important to ensure that intended payment efficiencies are realized, quality of care goals are achieved, and expenditures are proper.

Experience also teaches that payment structures can create incentives for misconduct that are attractive to unscrupulous providers. For example, fee-for-service payment systems can reward increased utilization, raising the risk of overutilization and payment for unnecessary services. Capitated payments, on the other hand, tend to reduce that risk but potentially incentivize inappropriate underutilization. Thus, understanding the applicable payment structure—including the way Federal funds flow and the financial incentives that are created—is fundamental to identifying and safeguarding against potential fraud and abuse.

Sound payment policy and practices take on added dimensions in the context of coordinated health care models. Accuracy of payments is particularly critical as payments become more complex and include additional variables around quality and performance. As to payment design, it is imperative that the program monitor medical practice and utilization changes and adjust payment designs accordingly to maintain incentives for quality and efficiency. Program officials will need to be sensitive to, and take steps to prevent, potential unintended impacts on utilization and patient care arising from payment design.<sup>27</sup> As to implementation, the Medicare program needs to set payments based on sound assumptions and accurate data, updating assumptions and payment rates accordingly. Finally, the program must ensure that providers submit accurate data and information for payment calculations in order to calculate payments and to test the accuracy of actual payments made.

### III. PROVIDER COMPLIANCE

Making significant changes in a program like Medicare requires that those involved in the change initiatives become partners, not just participants. Provider engagement in meaningful self-policing is essential to ensuring program integrity. Effective compliance programs help honest providers partner with government to tackle fraud, waste, and abuse. They also help providers improve their business operations and better manage business and legal risk. OIG has long assisted various

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27. OIG work addressing drug prices offers a cautionary example. *See OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., OEI-03-07-00440, BENEFICIARY UTILIZATION OF ALBUTEROL AND LEVALBUTEROL UNDER MEDICARE PART B* 1–2, 13, 18 (2009) (studying utilization rates of two similar asthma drugs). For this report, OIG studied Medicare Part B payments for two similar inhalation drugs used to treat the same indications. *Id.* at 1. One drug was significantly more expensive than the other. *See id.* at 1–2. OIG found that shifts in utilization patterns for the drugs coincided with changes in Medicare payment and coding. *Id.* at 13. Utilization of the more expensive drug increased when Medicare reimbursement for that drug was more favorable to suppliers; utilization shifted dramatically toward the less expensive drug when Medicare changed its pricing structure. *Id.*

sectors of the health care industry in adopting practices that promote voluntary compliance through guidance and training resources.<sup>28</sup> Congress' mandate in the Affordable Care Act that Medicare and Medicaid providers adopt compliance plans underscored the importance of provider compliance efforts.<sup>29</sup> The elements of an effective compliance program were first articulated in the sentencing guidelines for corporate violations in 1991<sup>30</sup> and are reflected in OIG's compliance resources.<sup>31</sup> These elements include: written policies and procedures, compliance professionals, effective training, effective communication, internal monitoring, enforcement of standards, and prompt response to problems and violations.<sup>32</sup>

A compliance program will only be successful if it is supported by a corporate culture committed to compliance and the aims of efficiency, economy, and effectiveness.<sup>33</sup> The governance and leadership of coordinated care organizations will play a vital role in fostering an accountable corporate culture.

Good governance and compliance must not only be directed at business operations and "bottom-line" returns, but must also focus on the quality of care and compliance with program rules. Provider compliance over the past two decades has tended to focus on business operations and regulatory compliance. In the new health care landscape, clinical care and quality will grow as compliance considerations.<sup>34</sup> Additional features of redesigned care coordination models, such as transparency and broad use of health information technology,<sup>35</sup> should assist in the development and operation of effective internal controls.

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28. See *Compliance*, OFFICE OF INSPECTOR GEN., <http://oig.hhs.gov/compliance> (last visited June 8, 2012) (providing links to OIG's compliance resources including compliance program guidance, advisory opinions, special fraud alerts and bulletins, training videos, and other resources).

29. Affordable Care Act, §§ 6401(a)(3),(b)(1), 6102 (current version at 42 U.S.C. §§ 1395cc(j)(8), 1396a(a)(77), 1320a-7j (Supp. 2011) (new requirements for providers in Medicare Parts A and B and Medicaid). Since 2003, Medicare Part D plan sponsors have been required to "adopt and implement an effective compliance program." 42 C.F.R. § 423.504(b)(4)(vi) (2011).

30. U.S. SENTENCING COMM'N, GUIDELINES MANUAL § 8B2.1 (2011); see also Paula Desio, *An Overview of the Organizational Guidelines*, U.S. SENTENCING COMM'N, [http://www.ussc.gov/guidelines/Organizational\\_Guidelines/ORGOVERVIEW.pdf](http://www.ussc.gov/guidelines/Organizational_Guidelines/ORGOVERVIEW.pdf) (last visited Apr. 2, 2012) (outlining the basic tenets of the guidelines).

31. See, e.g., OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4,858, 4,874–76 (Jan. 31, 2005).

32. *Id.*

33. For example, CMS recognized the importance of provider compliance in the SSP regulations by requiring ACOs to adopt compliance plans; to promote efficient compliance operations, the regulations permit coordination among the existing compliance operations of an ACO's providers. See Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,980 (Nov. 2, 2011) (to be codified at 42 C.F.R. § 425.300).

34. See generally *Highlights of the Keynote Address Delivered by Daniel Levinson, Inspector General of the Department of Health & Human Services, at the Health Care Compliance Association Annual Compliance Institute April 19, 2010*, OFFICE OF THE INSPECTOR GEN., <http://oig.hhs.gov/testimony/docs/2010/hccraigkeynotesummary.pdf>.

35. See BIPARTISAN POLICY CTR., TASK FORCE ON DELIVERY SYS. REFORM & HEALTH IT, DELIVERY SYSTEM REFORM AND THE ROLE OF HEALTH IT: AN INTERIM REPORT 5 (2011) ("[D]elivery

#### IV. MONITORING

Vigilantly monitoring for evidence of fraud, waste, and abuse is vital to protecting programs and patients. Technology, data, and advanced data analytics are essential tools to identify, track, and monitor billing patterns, utilization rates, and other indicia of potential problems. Rapid advances in capabilities and adoption of health information technology, as well as greater transparency, promise to aid in this critical function.<sup>36</sup> OIG and its government partners are engaged in enhancing monitoring capabilities through data systems designed to furnish a global picture of the Medicare environment and to support data analysis to quickly spot patterns of potentially troublesome claims and billing, including indications of clinical incoherence.<sup>37</sup> Data are also increasingly available from multiple program areas and data sources.<sup>38</sup> This more robust data environment enables the government to consider a wider range of data points—including geographic indicators, compromised billing numbers, and other pertinent data points—that inform an analysis of program integrity.

Focusing on claims is just one part of an effective monitoring approach, however. The government must also monitor quality of care and health care provider performance. Advances in technology and science will facilitate this effort.<sup>39</sup> Heightened attention to quality and performance is particularly critical in the context of coordinated care initiatives that reward participants for achieving quality, performance, and cost targets. The government must monitor to ensure that participants achieve those targets by improving care and appropriately reducing costs, not by gaming the system through improper methods such as avoiding expensive or difficult patients.<sup>40</sup> It is also incumbent on the participants themselves to monitor their operations. Important data for quality and performance

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system reforms that promote coordinated, accountable, patient-centered care cannot be attained without the support of an effective health [information technology] infrastructure.”).

36. See generally *Harnessing Technology and Innovation to Cut Waste and Curb Fraud in Federal Health Programs: Hearing Before the Subcomm. on Fed. Fin. Mgmt., Gov’t Info., Fed. Servs., and Int’l Sec., Comm. on Homeland Sec. & Gov’t Affairs*, *supra* note 16 (statement of Lewis Morris). Regrettably, health information technology can also aid the unscrupulous in committing fraud. *Id.* at 7-8.

37. See, e.g., 2011 ANNUAL REPORT, *supra* note 20 (discussing government methods to prevent waste, fraud, and abuse).

38. See generally *Harnessing Technology and Innovation to Cut Waste and Curb Fraud in Federal Health Programs*, *supra* note 36 (statement of Lewis Morris).

39. See, e.g., DEP’T OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS: NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE 12 (2011) (describing health information technology initiatives).

40. See, e.g., Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,973-82. The SSP calls for ACOs to be monitored for avoidance of at-risk beneficiaries and terminated for such conduct. *Id.* (to be codified at 42 C.F.R. § 425.316).

measurement are increasingly available to providers in a timely manner that facilitates better care and improved efficiency.<sup>41</sup>

Effective monitoring involves an evaluation of the potential risks, including any behavioral incentives created by payment structures, and calibration of the monitoring plan. The government must monitor the right areas in the right way. An example of the importance of carefully evaluating the risks and calibrating the monitoring strategy can be seen in the context of the SSP payment construct. Under the SSP, Medicare pays ACOs and their participating providers in two ways: first, providers are paid on an ordinary fee-for-service basis for the items and services they provide to beneficiaries; second, qualifying ACOs are paid a share of the cost savings they achieve each year.<sup>42</sup> This hybrid system involves the pairing of volume-based fee-for-service payments and shared savings payments. In these circumstances, an effective monitoring strategy must include robust monitoring for the range of potential risks inherent in both types of payments, including overutilization and underutilization. Effective monitoring, particularly early in a new program, will inform additional oversight efforts. For example, it will identify undesirable conduct so that the government may take prompt remedial action.

## V. GOVERNMENT REMEDIATION

Although preventing all fraud, waste, and abuse is the goal of oversight, there will never be perfect prevention. When fraud, waste, or abuse is detected, it is important for the government to respond swiftly to remediate the problem.<sup>43</sup> This effort often requires coordination among government partners to tailor an

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41. See, e.g., DATA.MEDICARE.GOV, <http://data.medicare.gov> (last visited June 8, 2012) (providing datasets, lists of contacts, and links regarding Medicare data); HOSPITAL COMPARE, <http://www.hospitalcompare.hhs.gov> (last visited June 8, 2012) (providing comparable data on hospitals).

42. Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,973, 67,986 (to be codified at 42 C.F.R. §§ 425.604, 425.606). Some ACOs will also assume downside risk for certain losses. *Id.* (to be codified at 42 C.F.R. § 425.600).

43. It is estimated that approximately three to as much as ten percent of all health care expenditures are attributable to fraud. See CLIFF BINDER, CONG. RESEARCH SERV., RL43127, MEDICARE PROGRAM INTEGRITY: ACTIVITIES TO PROTECT MEDICARE FROM PAYMENT ERRORS, FRAUD, AND ABUSE 9 (2011) ("Fraud analysts and law enforcement officials estimate that between three percent and ten percent of total health care expenditures (for all payers, including Medicare) are lost annually to fraud."); FBI, FINANCIAL CRIMES REPORT TO THE PUBLIC FOR FISCAL YEAR 2008 (2008), [http://www.fbi.gov/publications/financial/fcs\\_report2008/financial\\_crime\\_2008.htm#health](http://www.fbi.gov/publications/financial/fcs_report2008/financial_crime_2008.htm#health); NAT'L HEALTH CARE ANTI-FRAUD ASS'N, FIGHTING HEALTH CARE FRAUD: AN INTEGRAL PART OF HEALTH CARE REFORM 3 (2009); ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE, INSTITUTE OF MEDICINE, *Synopsis and Overview*, in THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES 53 (Pierre L. Yong ed., 2011) ("Additional areas suggested for consideration both in terms of targets and strategies included the issues such as costs of fraud and abuse, which has been estimated to cost 3 to 10 percent of total health spending. . . ."). Waste in health care represents a larger expenditure. Cf. David Lawrence, *Bridging the Quality Chasm*, in BUILDING A BETTER DELIVERY SYSTEM 99, 99 (Proctor P. Reid et al. eds., 2005) ("Between \$.30 and \$.40 of every dollar spent on health care is spent on the costs of poor quality.").

appropriate response. Responses can range from criminal or civil enforcement to administrative action, resolution of matters self-disclosed by providers,<sup>44</sup> or agency redesign of a program, process, or payment policy.

OIG has worked closely with its program and law enforcement partners to coordinate government remediation that is appropriate to the particular problem or concern. As earlier noted, it has done so, for example, through the HEAT Strike Forces designed primarily to attack criminal conduct concentrated in certain geographic areas around the nation, and through other initiatives that draw on investigative, prosecutorial, audit, and evaluative expertise to redress fraud and abuse. The spirit of cross-government cooperation has manifested itself in initiatives to streamline and consolidate data sources and work across portfolios to address issues holistically.

A sustained government commitment to respond to fraud, waste, and abuse will be critical in the twenty-first century health care environment. This response must be flexible and adaptable to emerging risks and program changes. Program integrity, including strong enforcement, must be a core value ingrained in the administration of coordinated care and other new payment and delivery models.

The SSP provides an interesting example of tailored approaches to oversight. The SSP introduced into the Medicare program ACOs designed to achieve better care and lower costs by moving from fragmented to coordinated care across providers.<sup>45</sup> To build ACOs, providers must come together in ways that, in some circumstances, implicate fraud and abuse laws addressing financial arrangements between and among prospective referral sources, such as hospitals and physicians.<sup>46</sup> These laws include the Federal anti-kickback statute,<sup>47</sup> the Physician Self-Referral Law,<sup>48</sup> and the Civil Monetary Penalties Law.<sup>49</sup> Among other things, these statutes

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44. Providers may voluntarily disclose and resolve self-identified violations through OIG's and CMS's self-disclosure protocols. See Publication of OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399, 58,400 (Oct. 30, 1998) (setting forth OIG's voluntary provider self-disclosure protocol); *Self-Referral Disclosure Protocol*, CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T HEALTH AND HUMAN SERVS. (last visited June 8, 2012), [https://www.cms.gov/PhysicianSelfReferral/98\\_Self\\_Referral\\_Disclosure\\_Protocol.asp](https://www.cms.gov/PhysicianSelfReferral/98_Self_Referral_Disclosure_Protocol.asp) (CMS's physician self-referral protocol).

45. Under the SSP, groups of providers, such as physicians and hospitals, form ACOs and work together to manage and coordinate care for Medicare fee-for-service beneficiaries. Affordable Care Act, § 3022 (current version at 42 U.S.C. § 1395jjj(a)(1)(A)). Those that meet quality and performance standards are qualified to receive, in addition to their customary reimbursement, a share of the savings they generate for the Medicare program. Affordable Care Act, § 3022 (current version at 42 U.S.C. § 1395jjj(a)(1)(B)).

46. See, e.g., Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 67,993 (Nov. 2, 2011).

47. 42 U.S.C. § 1320a-7b(b) (2006).

48. 42 U.S.C. § 1395nn (2006).

49. 42 U.S.C. § 1320a-7a (2006). Particularly relevant to the SSP are two provisions of the Civil Monetary Penalties law: the prohibition on hospital payments to physicians to reduce or limit services and the prohibition on beneficiary inducements. *Id.* §§ 1320a-7a(a)(5), (b)(1)-(2).

and corresponding regulations<sup>50</sup> set parameters for permissible financial relationships between referring parties.<sup>51</sup> Providers expressed concern that the constraints of these fraud and abuse laws would chill innovative business arrangements needed for ACOs to succeed.<sup>52</sup> For the SSP, Congress gave the Secretary of HHS authority to waive these laws “as necessary” to carry out the program.<sup>53</sup> However, nothing in the statute evidences any congressional intent to sanction the proliferation of the underlying harms addressed by these laws, such as overutilization, increased costs to Medicare, inappropriate patient steering, and stinting on care.

In promulgating the regulations that established waivers under this authority, CMS and OIG articulated the goal as “provid[ing] ACOs with flexibility, certainty, and latitude for beneficial innovation and variation in connection with the new [SSP], while also protecting Medicare beneficiaries and the Medicare program from fraud and abuse.”<sup>54</sup> To strike this balance, the SSP regulations and waiver regulations together included a comprehensive set of protections to safeguard the program and beneficiaries.<sup>55</sup> These protections included requirements that ACOs

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50. 42 C.F.R. § 1001.952 (2011) (safe harbor regulations under the Federal anti-kickback statute); 42 C.F.R. § 411.350 et seq. (Physician Self-Referral Law regulations).

51. See, e.g., Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 67,994–95 (describing legal authorities).

52. See, e.g., *id.* (“[S]takeholders have expressed concern that the restrictions these laws place on certain arrangements between physicians, hospitals, and other individuals and entities may impede development of some of the innovative integrated-care models envisioned by the Shared Savings Program.”). Stakeholders have also expressed similar concerns regarding the application of the fraud and abuse laws to integrated and coordinated care arrangements outside the context of the SSP. See, e.g., *id.* at 67,999 (summary of public comments on the need for waivers outside the SSP).

53. Affordable Care Act, § 3022(f) (current version at 42 U.S.C. § 1395jj(f) (2010)). Congress has addressed waivers of fraud and abuse laws elsewhere in connection with certain new Medicare and Medicaid payment and delivery models, including at section 5007 of the Deficit Reduction Act in connection with a specific gainsharing demonstration program (42 U.S.C. § 1395 note), and in other sections of the Affordable Care Act. See, e.g., Affordable Care Act, §§ 3026, 3023 (current version at 42 U.S.C. §§ 1315a(d)(1), 1395cc-5(e)(6)).

54. Final Waivers in Connection With the Shared Savings Program, 765 Fed. Reg. 67,992, 68,003. The waiver regulations, jointly issued by CMS and OIG, set forth five waivers available to ACOs that precisely meet specific waiver conditions. *Id.* at 67,999–68,001. The waivers address a spectrum of ACO arrangements from start-up arrangements to distributions of shared savings payments to certain incentives offered to patients to engage them in promoting their own health. *Id.* While most public respondents supported the waivers, some constituencies, private insurers among them, expressed reservations. See *id.* at 67,996, 67,998 (summarizing views of commenters). The waiver regulations were issued as part of an unprecedented suite of concurrent multi-agency guidance. See *Accountable Care Organizations*, OFFICE OF INSPECTOR GEN., U.S. DEPT’ HEALTH & HUMAN SERVS., <http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp> (last visited Feb. 29, 2012) (providing links to guidance from multiple Federal Agencies). In addition to the programmatic regulations issued by CMS and the waiver regulations, the antitrust agencies (the Federal Trade Commission and the Department of Justice Antitrust Division) and the Internal Revenue Service issued policy guidance related to the SSP. See *id.*

55. See Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 68,003 (Nov. 2, 2011). As noted in the preamble to the regulations:

operate in an accountable and transparent manner, as well as tools to allow the government to detect problems through rigorous monitoring of ACO operations and performance.<sup>56</sup> The government retained authorities to redress identified problems, including enforcement authorities that were not waived and administrative tools, such as program termination, corrective action plans, payment denials, and others.<sup>57</sup> The SSP waiver design was premised on an expectation that provider accountability and program integrity requirements embedded into the SSP and the waivers would mitigate the risk of harm in the first instance, and that residual risk could be remediated through appropriate government action.

## VI. CONCLUSION

As the SSP example suggests, oversight in the changing health care environment will need to be comprehensive and flexible, with robust tools to prevent, detect, and remedy instances of fraud, waste, and abuse. The outcomes of the SSP and other nascent initiatives are unknown. The SSP represents one experiment among many in the evolving health care system of the twenty-first century. As new programs develop and results become known, thoughtful evaluation of program outcomes and the utility of oversight strategies will be necessary. The government will need to adapt its approach to address detected vulnerabilities.

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[W]aivers rely, as a threshold matter, on the programmatic requirements of the Shared Savings Program to safeguard Medicare beneficiaries and the Medicare program. The design of the waivers is premised on our expectation that risks of fraud and abuse, such as overutilization, inappropriate utilization, and underutilization, will be mitigated, in the first instance, by the Shared Savings Program design, including, for example, the eligibility requirements, the quality of care and accountability provisions, and the program integrity provisions. In these waivers, we are adding additional safeguards in the form of governance responsibility, transparency, and a documented audit trail.

*Id.* The program rules set out these protections in detail. See Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802 (codified at 42 C.F.R. pt. 425).

56. See sources cited *supra* note 55.

57. See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67,992, 68,007–08. (stating that the government has a variety of tools to address fraud or other problems). As the preamble to the waiver regulations states:

The government's enforcement experience reflects that, to varying degrees, all Federal health care programs are susceptible to fraud and abuse. These waivers should not be read to reflect any diminution of our commitment to protect programs and beneficiaries from harms associated with kickbacks and referral payments, including overutilization, increased costs, and substandard or poor quality care. DHHS will monitor ACOs and the Shared Savings Program as a whole for fraud or abuse, such as billing for medically unnecessary or upcoded services, submitting false or fraudulent data, or providing worthless or substandard care. If these or other problematic practices are found, the government has a number of tools to address the problem. In appropriate cases, we will use these tools to protect the interests of beneficiaries and the Medicare program.

*Id.*

A new era is emerging, and not only for Medicare. New payment and delivery models involving coordinated care exist around the nation. Many private health insurers are contracting with provider groups to create models designed for patient-centered care, population health, and integrated provider service delivery. States are also exploring these models. The development, implementation, and application of coordinated and integrated health care models in an environment of accountability and transparency are viewed as crucial correctives in restoring greater financial and professional integrity.<sup>58</sup>

As Medicare adjusts to the new landscape, it will be critical for program officials and providers to place a sharp focus on ensuring accountability and transparency in the design and operation of these new programs. Providers must exercise sound judgment in creating robust governance structures equal to the task of making these new systems work as intended. Government and industry must demonstrate that new coordinated care delivery and payment models do what they promise, thereby rewarding successful industry participants, protecting the health of beneficiaries, and saving taxpayers from unnecessary public expense.

This is plainly a global responsibility, as effective oversight across health care models will require holistic and integrated approaches. All stakeholders must do their part, and with a joint and collective effort to ensure proper gatekeeping, sound payment, compliance, monitoring, and government remediation, Medicare and all who depend on it can look forward to a healthier and more secure future.

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58. See CTR. FOR THE EVALUATIVE CLINICAL SERVS., DARTMOUTH ATLAS PROJECT, THE CARE OF PATIENTS WITH SEVERE CHRONIC ILLNESS: A REPORT ON THE MEDICARE PROGRAM, EXECUTIVE SUMMARY 1, 4 (2006) (positing that transparency and integration will improve accountability and efficiency). As budgets tighten and policymakers seek new savings opportunities, tackling the problem of waste and inefficiency in the health care system will assume growing importance. See Lawrence, *supra* note 43, at 99 (noting that “[a] vast amount of money is wasted on overuse, underuse, misuse, duplication, system failures, unnecessary repetition, poor communication, and inefficiency”); CTR. FOR THE EVALUATIVE CLINICAL SERVS., *supra*; MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: REGIONAL VARIATION IN MEDICARE SERVICE USE 22 (2011). The greatest portion of estimated waste is attributable to inefficiencies; uneconomic practices; and ineffectiveness. Cf. Lawrence, *supra* note 43, at 99. Coordinated care, evidence-based medicine, and value based payment models offer promising opportunities for improved efficiency. In the future, advances in precision medicine may enhance the ability to ensure that high quality care is provided in a cost effective manner.