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Congressional Recipients

Subject: *Causes of Action under the Patient Protection and Affordable Care Act*

The Patient Protection and Affordable Care Act (PPACA) expands upon and establishes new health care quality enhancement initiatives. Although the goal of improving health care quality has garnered widespread support, some of PPACA's quality enhancement provisions have raised concerns among providers that they could unintentionally result in an increased litigation risk for those providers that do not follow the standards or guidelines used by these programs, perform poorly on the measures reported under these programs, or opt not to report performance on these standards and guidelines. For this reason, Congress directed GAO to consider whether the development, recognition, or implementation of any guideline or other standards under the 14 PPACA quality enhancement provisions identified in section 3512 of the law<sup>1</sup> would result in a "new cause of action or claim."<sup>2</sup> A cause of action or claim is a legal theory or set of facts that gives rise to a right to file a lawsuit.<sup>3</sup>

In response to this requirement, we considered whether implementation of the PPACA provisions could give rise to (1) new causes of action brought by private citizens to enforce compliance with guidelines, standards, and programs developed under the provisions or (2) new medical malpractice claims brought by individuals based on the guidelines or standards developed under the PPACA provisions. For the reasons discussed below, we do not believe that the implementation of the provisions identified in section 3512 of PPACA, including the development,

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<sup>1</sup> Throughout this report, we refer to these 14 PPACA provisions as the "PPACA provisions." See the enclosure for a complete list and description of the provisions.

<sup>2</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3512, 124 Stat. 119, 923 (Mar. 23, 2010) ("PPACA").

<sup>3</sup> Bryan A. Garner, *A Dictionary of Modern Legal Usage* 140, 159 (2d ed. 1995); see also Bryan A. Garner, ed., *Black's Law Dictionary* 214 (9<sup>th</sup> ed. 2009) (defining cause of action as "a factual situation that entitles one person to obtain a remedy in court from another person").

recognition, or implementation of related guidelines and standards, is likely to give rise to new causes of action or claims. Ultimately, the courts will determine, in the context of specific litigation, whether the PPACA provisions identified in section 3512 give rise to new causes of action or claims.

## BACKGROUND

To accomplish twin aims of improving quality and reducing costs, PPACA directs the Secretary of Health and Human Services (HHS) to establish new, or expand upon existing, Medicare and Medicaid quality-related provider reporting and payment programs. The law also calls for the development of quality and efficiency measures for use in federal health care programs. In addition, PPACA supports the development and dissemination of evidence-based care practices and clinical guidelines to improve individual patient care and community health.

These provisions, which are described in more detail in the table in the enclosure, largely build upon certain ongoing federal health care quality improvement activities.

### Quality-Related Provider Payment Provisions

PPACA extends Medicare's Physician Quality Reporting System (PQRS), under which Medicare professionals are eligible to receive incentive payments for reporting on select quality measures through 2014.<sup>4</sup> The law also expands the PQRS by reducing Medicare payments to professionals that fail to report on identified quality measures beginning in 2015.

PPACA modifies Medicare's Physician Feedback Program, which provides physicians with confidential reports that measure resources used to provide care to Medicare beneficiaries, including changing the type of reporting and data analysis for this program.<sup>5</sup>

Since federal fiscal year (FY) 2005, acute care hospitals have been required to submit quality data to receive the full Medicare annual payment update.<sup>6</sup> PPACA builds upon this program by directing the Secretary of HHS to establish incentive payments for hospitals that meet specified performance measures when treating Medicare patients.<sup>7</sup> The law also requires the Secretary to modify Medicare's

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<sup>4</sup> PPACA, §§ 3002, 10327, 124 Stat. at 363, 962. PQRS was initially established under the Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, Div. B, § 101, 120 Stat. 2922, 2975 (Dec. 20, 2006).

<sup>5</sup> PPACA, § 3003, 124 Stat. at 366. The Physician Feedback Program was established under the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 131(c), 122 Stat. 2494, 2526 (July 15, 2008).

<sup>6</sup> The requirement to submit quality data was initially established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 501, 117 Stat. 2066, 2289 (Dec. 8, 2003).

<sup>7</sup> PPACA, §§ 3001, 10335, 124 Stat. at 353, 974.

physician payment methodologies to allow variation of payment to physicians based on the relative quality and cost of care they provide.<sup>8</sup>

Since FY 2009, Medicare has prohibited inpatient hospital reimbursement for treatment of certain hospital-acquired conditions (HACs) not present on admission.<sup>9</sup> PPACA expands upon this prohibition by requiring the reduction of base Medicare inpatient payments for hospitals with high rates of HACs and extends this concept to the Medicaid program by prohibiting federal Medicaid payments for preventable health care-acquired conditions.<sup>10</sup> The law similarly reduces Medicare inpatient reimbursement to hospitals with higher-than-average readmission rates.<sup>11</sup>

In addition, PPACA requires the Secretary of HHS to establish a new Center for Medicare and Medicaid Innovation for the purpose of authorizing demonstrations that test payment and service delivery models designed to reduce cost while preserving quality of care.<sup>12</sup>

### Development of Quality and Efficiency Measures

PPACA directs federal agencies to take steps to develop and adopt quality and efficiency measures to be used in federal health care programs.

PPACA directs the Secretary of HHS in consultation with the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) to identify gaps in quality and efficiency measures and to undertake a process for developing and adopting measures for use in federal programs, including consideration of multi-stakeholder group recommendations on the selection of such measures.<sup>13</sup> The law also directs HHS to develop a recommended set of health quality measures for Medicaid eligible adults and to encourage states to develop reporting systems to collect Medicaid provider performance data on such measures.<sup>14</sup>

### Quality Improvement Strategies and Care Recommendations

PPACA also contains provisions aimed at facilitating overall health care quality improvement, including through the development and dissemination of quality improvement strategies and the provision of funding for research into

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<sup>8</sup> PPACA, § 3007, 124 Stat. at 373.

<sup>9</sup> Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5001(c), 120 Stat. 4, 30 (Feb. 5, 2006).

<sup>10</sup> PPACA, §§ 2702, 3008, 124 Stat. at 318, 376.

<sup>11</sup> PPACA, §§ 3025, 10309, 124 Stat. at 408, 942.

<sup>12</sup> PPACA, §§ 3021, 10306, 124 Stat. at 389, 939.

<sup>13</sup> PPACA, §§ 3013, 3014, 10303, 10304, 124 Stat. at 381, 384, 937-38.

<sup>14</sup> PPACA, § 2701, 124 Stat. at 317.

evidence-based practices to improve public health services and health systems.<sup>15</sup> The law also calls on the U.S. Preventive Services Task Force and the Community Preventive Services Task Force to issue clinical preventive care recommendations and to develop community preventive services recommendations to improve overall population health.<sup>16</sup>

To analyze whether any of these provisions, or the implementation thereof, could give rise to new causes of action or claims, we reviewed the PPACA provisions, implementing regulations and related guidance, and federal case law describing the criteria for establishing new causes of action. We also reviewed treatises and other legal resources regarding tort law principles.

## DISCUSSION

### Creation of New Causes of Action to Enforce Compliance with Quality Standards and Guidelines Promulgated Under PPACA and PPACA's Quality-Related Payment Programs

The United States Supreme Court has held that only Congress has the authority to establish a private right of action.<sup>17</sup> In particular, the Court has held that a regulation may not create a private right of action unless Congress intended to create such a right in the particular provision the regulation seeks to implement.<sup>18</sup> Congressional intent is determinative as to whether a private right of action exists.<sup>19</sup> Therefore, our analysis of whether private citizens may seek to enforce compliance with the quality standards and guidelines promulgated under the PPACA provisions and PPACA's quality-related payment programs centers on the statutory provisions under which standards and guidelines are to be developed, implemented, or recognized. Specifically, we look to the plain language of the provisions themselves.

The statutory provisions included in our review require the development of quality and efficiency measures for use in federal health care programs, payment adjustments based on provider reporting and performance, and the development of clinical care guidelines for health care practitioners. None of these provisions explicitly establish a private right of action to obtain a provider's compliance with those measures or guidelines or with the law's quality-related payment provisions.

The Court has recognized that statutory provisions that do not explicitly establish a private right of action may be interpreted to create a private right of action if

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<sup>15</sup> PPACA, §§ 3501, 4301, 10501(f)(2), 124 Stat. at 507, 578, 996.

<sup>16</sup> PPACA, § 4003, 124 Stat. at 541.

<sup>17</sup> See, e.g., *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001); *California v. Sierra Club*, 451 U.S. 287, 293 (1981); *Touche Ross & Co. v. Redington*, 442 U.S. 560, 568 (1979); *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 15-16 (1979).

<sup>18</sup> *Alexander*, 532 U.S. at 291.

<sup>19</sup> *Id.* at 286-87.

Congress intended to create such a private right.<sup>20</sup> The Court has outlined the following four-part test for determining whether Congress intended to create an implied right of action: (1) whether the statute was enacted for the special benefit of the individual filing suit—that is, does the statute create a federal right in favor of the plaintiff; (2) whether the law’s legislative history suggests that Congress intended to create a private right of action or to deny one; (3) whether providing a private right of action is consistent with the law’s design; and (4) whether the right of action is one that traditionally would be based in state, rather than federal, law.<sup>21</sup> Applying this test to the statutory provisions included in our review, we believe a court would be unlikely to find that Congress created an implied right of action in adopting any of the provisions outlined in section 3512 of PPACA.

(1) Whether the statute was enacted for the special benefit of the individual filing suit

The PPACA provisions do not establish the type of special benefit required for an implied right of action. The Court has held that a statute that focuses on a regulated party rather than on an individual who might be harmed by the activity that the statute regulates was not enacted for the special benefit of the individual and, therefore, does not create an implied private right of action.<sup>22</sup> Most of the provisions we reviewed direct the Secretary of HHS to vary payment to Medicare providers, which are regulated parties by virtue of their participation in Medicare, based upon the providers’ submission of certain performance data or providers’ performance on certain quality of care measures;<sup>23</sup> others foster the development of measures or guidelines related to the delivery of care. Absent from each of the 14 provisions is the type of “rights-creating” language that is necessary to imply a private right of action. Such language “expressly identifies the class Congress intended to benefit,” in contrast to statutes that are enacted for the protection or benefit of the general public and which impose obligations or prohibitions on regulated entities or persons.<sup>24</sup> For example, the Court in *Cannon v. University of Chicago* found that Title IX of the Education Amendments Act of 1972, which provides that, “No person

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<sup>20</sup> See, e.g., *id.* (“Without [congressional intent], a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute.”); *Transamerica Mortgage Advisors, Inc.*, 444 U.S. at 15-16 (“what must ultimately be determined is whether Congress intended to create the private remedy”).

<sup>21</sup> *Cort v. Ash*, 422 U.S. 66, 78 (1975); see also *California*, 451 U.S. at 293; *Cannon v. University of Chicago*, 441 U.S. 677, 689 (1979).

<sup>22</sup> *California*, 451 U.S. at 294-95 (finding that the Rivers and Harbors Appropriation Act of 1899, which prohibited certain activities, but did not identify any particular class of beneficiaries of the law’s protections did not create a private right of action).

<sup>23</sup> For example, section 3002 provides Medicare incentive payments to those professionals who satisfactorily report on applicable quality measures and section 3025 requires the Secretary to reduce Medicare reimbursement for acute care hospitals with readmission rates exceeding a certain level. 124 Stat. at 376, 408, 942.

<sup>24</sup> *Cannon*, 441 U.S. at 690-91 (1979).

in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance,” contained such rights-creating language and accordingly provided a private right of action for those alleging sex discrimination by federally supported medical schools.<sup>25</sup> In contrast, the Court in *California v. Sierra Club* found that the Rivers and Harbors Appropriation Act of 1899, which prohibited certain activities on navigable waterways without identifying a particular class of beneficiaries, did not contain such rights-creating language and therefore did not create a private right of action.<sup>26</sup> As the Court stated, “[t]he question is not simply who would benefit from the [law], but whether Congress intended to confer federal rights upon those beneficiaries.”<sup>27</sup>

Certainly, Medicare beneficiaries and others who receive health care from providers who adhere to the PPACA provisions, and the guidelines and standards developed under these provisions, may receive higher quality care because of the incentives that these provisions extend to providers to improve the quality of the care they provide. Conversely, those who receive care from providers who fail to do so may receive lower quality care. However, nothing in the provisions suggests that Medicare beneficiaries or other individuals have a right to receive care from providers that satisfactorily report performance data or achieve a certain level of performance under the provisions.<sup>28</sup> Nor does anything in the provisions requiring the development of quality measures for use in federal health care programs suggest that such a right exists. Similarly, while those provisions requiring the development of quality improvement strategies and clinical practice guidelines aim to generally improve quality of care and to encourage adherence to evidence-based medical practices, the mere creation of these strategies and guidelines does not provide individuals a right to receive health care that reflects those strategies and guidelines and a corresponding right of action under federal law.

Moreover, not only is it the case that the PPACA provisions do not focus on those individuals who might benefit from them, but also they do not focus on the providers those provisions are designed to impact. Rather, these provisions either direct the Secretary of HHS to take steps to vary payment to certain providers or require the Secretary or applicable federal agency or task force to foster the development of health care quality measures, quality improvement strategies, and clinical practice guidelines. As such, these provisions are, in the words of the Court in *Alexander v.*

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<sup>25</sup> 441 U.S. at 681, 690-94.

<sup>26</sup> 451 U.S. at 294.

<sup>27</sup> *Id.*; cf. *Cannon*, 441 U.S. at 690 (noting that those statutes that the Court has found to provide a private right of action contain language, “which expressly identifies the class Congress intended to benefit [and] contrasts sharply with statutory language customarily found in criminal statutes, such as that construed in *Cort*, *supra*, and other laws enacted for the protection of the general public”).

<sup>28</sup> Indeed, as the Court stated in *Cannon*, “the fact that a federal statute has been violated and some person harmed does not automatically give rise to a private cause of action in favor of that person.” *Cannon*, 441 U.S. at 688.

*Sandoval*, “yet a step further removed” from those that create a private right of action because they neither focus on the individuals who will benefit from the statute nor on those regulated entities they will affect.<sup>29</sup> In *Alexander*, the Court considered whether section 602 of Title VI of the Civil Rights Act of 1964, which authorizes federal agencies to issue rules, regulations, or orders to carry out the law’s prohibition on discrimination on the basis of race, color, or national origin, established a private right of action. In holding that section 602 did not establish such a right, the Court noted that the provision was “twice removed from the individuals who will ultimately benefit from Title VI’s protection,” as the provision simply was “phrased as a directive to federal agencies engaged in the distribution of federal funds.”<sup>30</sup>

(2) Whether the law’s legislative history suggests that Congress intended to create a private right of action

We found no evidence in PPACA’s legislative history that suggests Congress intended to create an implied right of action to enforce the 14 provisions identified in section 3512. To the contrary, the legislative history suggests that Congress explicitly did not intend to establish any private rights of action in adopting these provisions. In a floor statement during the House of Representatives’ debate on the law’s final passage, Representative Henry Waxman stated, “It is not and never has been the intent of this legislation to create any new causes of action or claims premised on the development of guidelines or other standards.”<sup>31</sup> Two days after the President signed PPACA into law, Senator Diane Feinstein echoed Representative Waxman’s remarks on the Senate floor, stating “it has never been the intent of the bill to create any new causes of action . . . .”<sup>32</sup>

The Supreme Court has held that where the first two factors suggest that Congress did not intend to establish a private right of action, it is unnecessary to consider whether a private right of action is consistent with a law’s design or whether such a right of action traditionally would be based in state, rather than federal, law.<sup>33</sup> Although we believe, based on our analysis of the first two factors, that courts would be unlikely to determine that Congress intended to establish a private right of action

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<sup>29</sup> 532 U.S. at 289.

<sup>30</sup> *Id.* (quoting *Univ. Research Ass’n, Inc. v. Coutu*, 450 U.S. 754, 772 (1981)). In contrast, the Court has held that private individuals may bring a cause of action to enforce section 601 of Title VI, which prohibits discrimination based on race, color, or national origin in programs or activities that receive federal financial assistance. See *id.* at 279.

<sup>31</sup> 156 Cong. Rec. H1857 (daily ed. Mar. 21, 2010).

<sup>32</sup> *Id.* at S2079 (Mar. 25, 2010). Although the weight afforded to non-contemporaneous legislative history is limited, the Court has considered such legislative history as indicative of congressional intent regarding the creation of private rights of action. Specifically, in *Cannon*, the Court noted it “would be remiss” if it did not consider as authoritative congressional statements regarding the scope and purpose of Title IX that were made several years after that law’s enactment. *Cannon*, 441 U.S. 688.

<sup>33</sup> See, e.g., *California*, 451 U.S. at 297-98.

under the PPACA provisions, we briefly discuss our analysis of these provisions under the final two factors.

(3) Whether an implied right of action is consistent with the law's design

As discussed above, none of the PPACA provisions impose any affirmative obligations on providers to achieve a specified level of performance. Therefore, we believe a court would likely find that an implied private right of action under these provisions is inconsistent with the law's design. Not only do these provisions lack the type of "rights-creating" language necessary to imply a private right of action, but also several of the provisions contain express direction to the implementing agency as to how they are to be enforced. For example, section 3002 provides for Medicare incentive payments to those professionals who satisfactorily report on applicable quality measures, and section 3025 requires the Secretary to reduce Medicare reimbursement for acute care hospitals with readmission rates exceeding certain levels. According to the Court, although the inclusion of such enforcement provisions in the statutory text is not itself dispositive of whether the law provides for a private right of action, it "tend[s] to contradict a congressional intent to create privately enforceable rights."<sup>34</sup> In the absence of evidence of congressional intent to establish such rights, the existence of these provisions lends further support to the argument that Congress did not intend to establish a private right of action.

(4) Whether the right of action would traditionally be based in state, rather than federal law

The practice of medicine is traditionally governed by state law, and consequently it is unlikely Congress intended to establish a federal private right of action to enforce provider adherence to quality measures developed in response to federal law.<sup>35</sup> Although a cause of action to enforce compliance with a federal reporting obligation would fall within the jurisdiction of the federal courts, we believe that a court would be unlikely to find an implied right of action based on this fact alone.

For the foregoing reasons, we do not believe that the federal courts would interpret any of the PPACA provisions as giving rise to new private rights of action. Because we do not believe that Congress intended to create any private rights of action in adopting these provisions, it is also our view that the development, recognition, or implementation of standards or guidelines under these provisions is unlikely to give rise to new private rights of action.

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<sup>34</sup> *Alexander*, 532 U.S. at 290; *cf. Cannon*, 441 U.S. 704-08 (finding that an implied private right of action to enforce Title IX's ban on sex discrimination was not inconsistent with the law's procedure for terminating federal financial support for institutions that engage in discriminatory practices).

<sup>35</sup> 61 Am.Jur. 2d Physicians, Surgeons, and Other Healers § 10 ("Fundamentally, the power to regulate the practice of the healing arts is vested in the state legislatures and constitutes a field of legislative control over which the Federal Government has no jurisdiction.").

## Creation of New Medical Malpractice Claims

In addition to new causes of action to enforce compliance with the standards and guidelines developed, recognized, or implemented under the law, as well as PPACA's quality-related payment provisions, we also consider whether the PPACA provisions could give rise to new medical malpractice claims. In contrast to the question of whether the statutory provisions create new causes of action, which is a matter of federal law that would be adjudicated in federal court,<sup>36</sup> medical malpractice claims are typically governed by state tort law and are generally litigated in state court.<sup>37</sup> Therefore, we address this question in the context of well-established principles of tort law.

A medical malpractice claim is a type of negligence claim.<sup>38</sup> To successfully bring such a claim, an injured patient must show that the provider was negligent, that the patient suffered damages, and that the provider's negligence was the proximate cause of the patient's injuries.<sup>39</sup> In a medical malpractice action, negligence is generally determined with regard to whether the physician's conduct in treating the patient met the standard of care to which physicians of the same or similar localities in the state, or across the country, adhere.<sup>40</sup> In addition, specialists generally are held to the standard of care for the specialty, which is uniform and national.<sup>41</sup> The standard of care in a medical malpractice action is typically established on a case-by-case basis through the testimony of expert witnesses.<sup>42</sup>

In some cases, violations of a statute establish a presumption of negligence.<sup>43</sup> Violations of ordinances or administrative regulations also may establish such a presumption. In such cases, even if the statute does not expressly establish a new negligence claim, a court nevertheless may determine that a statute that regulates certain types of conduct gives rise to a negligence claim when the law is violated.

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<sup>36</sup> The federal district courts have original jurisdiction over civil actions arising under federal laws. 28 U.S.C. § 1331.

<sup>37</sup> Federal courts may hear actions involving state law claims where the matter in controversy exceeds \$75,000 and the litigants are citizens of different states. 28 U.S.C. § 1332. Although medical malpractice claims typically are governed by state law, the Federal Tort Claims Act, codified at 28 U.S.C. §§ 1346, 2671-2680, provides a legal mechanism for compensating individuals who have suffered personal injury as a result of a federal government employee's negligent or wrongful action. This includes certain health care providers, such as those employed by federally qualified health centers.

<sup>38</sup> 2 Dan B. Dobbs et al., *The Law of Torts* § 283 (2d ed. 2011).

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at §§ 283, 297.

<sup>41</sup> *Id.* at § 298.

<sup>42</sup> *Id.* at § 283. In some cases, courts may apply a reasonable care standard under which a jury must determine whether the risk of the provider's conduct outweighed its potential benefits, regardless of medical custom. *Id.*

<sup>43</sup> Restatement (Third) of Torts § 14 (2010); 1 Dobbs, at § 148.

To give rise to such implied negligence, commonly referred to as negligence *per se*, a statute must be designed to protect against a particular type of conduct and must be intended to protect the individual who is injured.<sup>44</sup> For example, a court may find that a driver who injured another driver while driving above the speed limit was negligent *per se* because the driver violated a statute that was designed to protect against the type of accident that the driver's conduct caused.

None of the PPACA provisions explicitly establish a basis for a new medical malpractice claim against a provider who fails to adhere to the guidelines or standards issued under these provisions. We believe it is unlikely that a court would find that a provider's failure to adhere to the quality and efficiency measures or clinical practice guidelines promulgated under the PPACA provisions constitutes negligence *per se* because these PPACA provisions are not designed to prohibit certain types of conduct; nor are they specifically designed to protect individuals receiving care.<sup>45</sup> Rather, most of the provisions are designed to provide incentives to providers to report to the government their performance on certain measures so that the government and the public may assess quality and efficiency of care and to provide incentives to providers to improve the quality of care they deliver. Other provisions simply require the development and dissemination of medical best practices to improve care. In this regard, these standards or guidelines are voluntary, and a failure to adhere to them is unlikely to be considered evidence of negligence *per se*.<sup>46</sup>

Although the provisions identified in section 3512 of PPACA are unlikely to give rise to new medical malpractice claims or to result in a finding of negligence *per se*, it is possible that, over time, the guidelines and standards developed, recognized, and implemented under these provisions could shape the standard of care against which a provider's conduct is measured in a medical malpractice lawsuit. As discussed, in a medical malpractice action, a provider's conduct is evaluated in terms of the standard of care, which is generally established through the testimony of an expert witness, whose testimony is likely to be based either on his or her own experience or

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<sup>44</sup> *Id.*

<sup>45</sup> In addition to concerns about whether the standards or guidelines developed, recognized, or implemented under PPACA could lead to new medical malpractice claims, we understand that some providers also have expressed concern that injured patients could seek to use publicly available performance data as evidence against them in medical malpractice actions, as section 3015 of PPACA requires HHS to publicly report performance information for those providers from whom the agency collects quality-related information. However, such information is reported by HHS in the aggregate and not on a patient-by-patient basis and may be difficult to use in determining whether a provider was negligent in treating a particular patient.

<sup>46</sup> Restatement (Third) of Torts § 13 cmt. e (2010) (Violations of voluntary standards issued by a public agency do not give rise to negligence *per se*. They, however, may be admissible as evidence of negligence in cases where the standards incorporate existing customs or have widespread adherence.).

on his or her observations of the relevant medical standard of care.<sup>47</sup> As a result, to the extent that these guidelines and standards become generally accepted as the standard of care by the relevant medical community, they may shape an expert's own experience or his or her observations of the relevant medical standard of care.

In addition, an expert's views may be explicitly informed by these standards or guidelines, with an expert drawing directly from them when testifying in a particular medical malpractice action as to whether a particular provider's actions did or did not comport with the standard of care.<sup>48</sup> A court may or may not admit such guidelines or standards into evidence in a medical malpractice trial.<sup>49</sup> Whether such evidence is admitted ultimately is a function of the evidentiary standards in place in a particular jurisdiction, as well as a particular judge's determination of how to apply such standards.<sup>50</sup> At a minimum, however, a court is likely to consider whether the standards or guidelines or provider's performance on them are relevant to determining whether a provider is negligent.<sup>51</sup>

Relevant evidence is evidence that tends to make a determinative fact in a case more or less likely and is material to the case.<sup>52</sup> Whether a particular guideline or standard is relevant in a particular case may depend, for example, upon whether the recommendation in the standard or guideline is applicable to the injured patient and whether the guideline or standard is pertinent to the provider's approach to treating a patient.<sup>53</sup>

Once admitted into evidence, courts may assign varying degrees of weight to the standards or guidelines.<sup>54</sup> In contrast to a violation of a statute that constitutes negligence *per se*, however, a finding that a provider did not adhere to the standard of care does not necessarily require the jury to find the provider negligent.<sup>55</sup> Rather,

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<sup>47</sup> 2 Dobbs, at § 303; see also Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 Univ. Pa. L. Rev. 645, 660 (2001).

<sup>48</sup> Mello, at 660.

<sup>49</sup> *Id.* at 663; see also Restatement (Third) of Torts § 13 cmt. e (2010).

<sup>50</sup> Mello, at 663.

<sup>51</sup> See Fed. R. Evid. 402 ("All relevant evidence is admissible except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.")

<sup>52</sup> Fed. R. Evid. 401.

<sup>53</sup> See Finder, Jodi M., "The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?," 10 Health Matrix: Journal of Law-Medicine 67, 81-83 (Winter 2000).

<sup>54</sup> See Mello, at 665 (noting that courts may assign varying weight to clinical practice guidelines admitted into evidence in medical malpractice actions).

<sup>55</sup> Restatement (Third) Torts § 13 (2010).

it is simply evidence of possible negligence, or, in the event the provider followed the relevant standard or guideline, evidence that the provider was not negligent.<sup>56</sup>

Because nothing in the PPACA provisions explicitly establishes a new medical malpractice claim, we believe the courts are unlikely to find that the provisions give rise to such new claims. We also believe the courts are unlikely to consider a provider's lack of adherence to the guidelines and standards established under these provisions to be evidence of negligence *per se*. However, it is possible that if these guidelines and standards become widely adopted they could impact how the standard of care is defined in a particular medical malpractice action.

## CONCLUSION

The determination as to whether the development, recognition, or implementation of guidelines or standards promulgated under the provisions identified in section 3512 of PPACA, or the implementation of the law's quality-related payment provisions, give rise to new causes of action or claims ultimately rests with the courts. Based on our analysis, we do not believe that the courts would be likely to find such new causes of action or claims. However, it is possible that, if these standards and guidelines become accepted medical practice, they could impact the standard of care against which provider conduct is assessed in medical malpractice litigation.



Lynn H. Gibson  
General Counsel

Enclosure

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<sup>56</sup> *Id.*

## List of Recipients

The Honorable Harry Reid  
Majority Leader  
The Honorable Mitch McConnell  
Minority Leader  
United States Senate

The Honorable John Boehner  
Speaker  
The Honorable Nancy Pelosi  
Minority Leader  
House of Representatives

The Honorable Max Baucus  
Chairman  
The Honorable Orrin G. Hatch  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Tom Harkin  
Chairman  
The Honorable Michael B. Enzi  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Henry Waxman  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Dave Camp  
Chairman  
The Honorable Sander Levin  
Ranking Member  
Committee on Ways and Means  
House of Representatives

Enclosure

**Table of Provisions Subject to GAO Study under Section 3512 of PPACA**

Provision	Description	Implementation
<p><b>§ 2701</b>  <b>Medicaid Adult Health Quality Measures<sup>1</sup></b></p>	<p>Directs the Secretary of Health and Human Services (HHS) to identify and publish a recommended core set of health quality measures for Medicaid-eligible adults by January 1, 2012. Also directs the Secretary, by January 1, 2013, to develop a standardized reporting format using these measures and to create procedures to encourage states to use these measures to voluntarily report state-specific information on the quality of care provided to Medicaid-eligible adults. Also requires states to annually report on the state-specific adult health quality measures identified in the state Medicaid plan. By September 30, 2014, the Secretary must collect, analyze, and make publicly available this reported information.</p>	<p>HHS issued the final core set of measures on January 4, 2012.<sup>2</sup></p>
<p><b>§ 2702</b>  <b>Medicaid Payment Adjustment for Health Care-Acquired Conditions<sup>3</sup></b></p>	<p>Requires the Secretary of HHS to identify current state practices that prohibit reimbursement for health care-acquired conditions (HCACs) and, as appropriate, to prohibit, through regulation, federal Medicaid matching funds for any amounts expended for designated HCACs.</p>	<p>The Centers for Medicare &amp; Medicaid Services (CMS) issued a final rule prohibiting federal Medicaid payment for most health care-acquired conditions for which payment is prohibited under the Medicare</p>

<sup>1</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2701, 124 Stat. 199, 317 (Mar. 23, 2010) (PPACA).

<sup>2</sup> *Medicaid Program: Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults*, 77 Fed. Reg. 286 (Jan. 4, 2012).

<sup>3</sup> PPACA, § 2702, 124 Stat. at 318.

		program and certain provider-preventable conditions on June 6, 2011. <sup>4</sup>
<b>§ 3001</b> <b>Medicare Hospital Value-Based Purchasing Program</b> <sup>5</sup>	Directs the Secretary of HHS to establish a hospital value-based purchasing program under which HHS will make incentive payments to hospitals for discharges of Medicare patients on or after October 1, 2012, for meeting identified performance measures.	On May 6, 2011, CMS issued a final rule to implement a Medicare hospital value-based purchasing program. <sup>6</sup>
<b>§ 3002</b> <b>Medicare Physician Quality Reporting Improvements</b> <sup>7</sup>	Extends incentive payments for quality reporting for Medicare professionals through 2014, and, beginning in 2015, imposes a payment penalty on eligible Medicare professionals who fail to satisfactorily report on the applicable quality measures.	CMS finalized quality measures for calendar year (CY) 2012 in its CY 2012 Physician Fee Schedule rule with comment period published on November 28, 2011. <sup>8</sup>

<sup>4</sup> *Medicaid Program; Payment Adjustment for Provider-Preventable Conditions Including Health Care-Acquired Conditions*, 76 Fed. Reg. 32816 (June 6, 2011). The final rule postpones implementation of the provider-preventable conditions payment prohibition until July 1, 2012.

<sup>5</sup> PPACA, §§ 3001, 10335, 124 Stat at 353, 974.

<sup>6</sup> *Medicare Programs; Hospital Inpatient Value-Based Purchasing Program*, 76 Fed. Reg. 26490 (May 6, 2011).

<sup>7</sup> PPACA, §§ 3002, 10327, 124 Stat. at 363, 962.

<sup>8</sup> *Medicare Program; Payment Policies under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition*, 76 Fed. Reg. 73026 (Nov. 28, 2011).

<p><b>§ 3003</b> <b>Medicare Physician Feedback Program Improvements<sup>9</sup></b></p>	<p>Requires new reporting and data analyses for the existing Physician Feedback Program, through which the Secretary of HHS provides reports to physicians who render services to Medicare beneficiaries. Specifically, this provision directs the Secretary to develop a Medicare-specific episode grouper that combines separate but clinically related items and services into an episode of care for an individual. Beginning in 2012, the Secretary is required to provide confidential reports to physicians, using this methodology, that compare their patterns of resource use with the patterns of other physicians.</p> <p>The methodology for attributing episodes of care to physicians, identification of appropriate physicians for comparison purposes, aggregation of episodes of care attributed to a physician, making adjustments to data and aggregate physician reports will be publicly available; however, individual physician reports will be confidential.</p>	<p>In a proposed rule, CMS announced ongoing development of an episode grouper for a subset of high cost, high volume conditions for Medicare beneficiaries. Testing and plans to seek third party endorsement of this episode grouper are underway.<sup>10</sup></p>
<p><b>§ 3007</b> <b>Medicare Physician Value-Based Modifier Program<sup>11</sup></b></p>	<p>Directs the Secretary of HHS to establish a value-based payment modifier for the Medicare physician fee schedule that varies payment to physicians and physician groups based upon the relative quality and cost of care they provide. Requires the Secretary to publish the quality and cost measures to evaluate physicians and physician groups with respect to this modifier. The Secretary must apply this payment modifier for items and services furnished beginning on January 1, 2015, for specified physicians and groups of physicians, and not later than January 1, 2017, for all physicians and groups of physicians.</p>	<p>CMS announced the initial quality and cost measures for the value-based payment modifier in its CY 2012 Physician Fee Schedule rule with comment period published on November 28, 2011.<sup>12</sup></p>

<sup>9</sup> PPACA, § 3003, 124 Stat. at 366.

<sup>10</sup> *Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012*, 76 Fed. Reg. 42772 (July 19, 2011).

<sup>11</sup> PPACA, § 3007, 124 Stat. at 373.

<sup>12</sup> 76 Fed. Reg. 73026 (Nov. 28, 2011).

<p><b>§ 3008</b></p> <p><b>Medicare Payment Adjustment for Hospital-Acquired Conditions<sup>13</sup></b></p>	<p>Medicare generally pays acute care hospitals based on a patient's assigned diagnosis. Hospitals may receive additional payments for secondary diagnoses. Beginning in October 2008, hospitals were prohibited from receiving these additional payments when their patients had certain hospital-acquired conditions (HACs).<sup>14</sup> Beginning in FY 2015, acute care hospitals in the top quartile of national risk-adjusted HAC rates for an applicable period will receive 99% of what they would have otherwise received in Medicare reimbursement. Prior to 2015, the Secretary of HHS must provide hospitals with reports of their HAC rates and once hospitals have reviewed their reports, this information will be posted on the Hospital Compare Web site.</p>	<p>In October 2011, CMS began publishing hospital-specific HAC data on the Hospital Compare Web site.<sup>15</sup></p>
<p><b>§ 3013</b></p> <p><b>Quality Measurement Development<sup>16</sup></b></p>	<p>Directs the Secretary of HHS, in consultation with the Agency for Healthcare Research and Quality (AHRQ) and CMS, to identify gaps in quality measures<sup>17</sup> for use in federal health care programs, to make a report of such gaps available on the Internet, and to enter into agreements with eligible entities to develop, improve, update, or expand these measures.</p> <p>Also directs the Secretary of HHS to develop and periodically update provider-level outcome measures for acute and chronic diseases and primary and preventive care.</p>	<p>CMS's Quality Measurement and Health Assessment Group in the Office of Clinical Standards and Quality is responsible for overseeing the development, implementation, and maintenance of health care quality measures.</p>

<sup>13</sup> PPACA, § 3008, 124 Stat. at 376.

<sup>14</sup> Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5001(c), 120 Stat. 4, 30 (Feb. 8, 2006).

<sup>15</sup> Hospital Compare, [www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov) (last visited Mar. 15, 2012). HAC data is expressed as the number of HACs per 1,000 discharges.

<sup>16</sup> PPACA, §§ 3013, 10303, 124 Stat. at 381, 937.

<sup>17</sup> Section 3013(a) defines the term "quality measure" as "a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services."

<p><b>§ 3014</b> <b>Quality Measurement</b><sup>18</sup></p>	<p>Directs the consensus-based entity under contract with CMS (currently, the National Quality Forum (NQF)) to convene multi-stakeholder groups to provide input on the selection of quality and efficiency measures for the Secretary to use in health care programs, including Medicare, in reporting performance information to the public. Also directs the entity to identify gaps in the quality measurement portfolio in relation to the National Quality Strategy, and to report on the groups' recommendations to the Secretary of HHS on an annual basis.</p> <p>Requires the Secretary to establish a pre-rulemaking process for the adoption, dissemination, and review of the groups' recommendations, and a process for disseminating and reviewing quality and efficiency measures adopted by the Secretary.</p>	<p>NQF has convened the Measure Applications Partnership (MAP) to provide input to HHS on the performance measures under consideration for public reporting and performance-based payment programs. In December 2011, CMS sought MAP's input on 366 new measures for use in 23 CMS programs, and MAP provided pre-rulemaking input on the selection of measures to HHS in February 2012.</p>
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<sup>18</sup> PPACA, § 3014, 10304, 124 Stat. at 384, 938.

<p><b>§ 3021</b> <b>Center for Medicare and Medicaid Innovation</b><sup>19</sup></p>	<p>Requires the Secretary of HHS to establish the Center for Medicare and Medicaid Innovation (CMI) within CMS by January 1, 2011 for the purpose of testing innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and CHI, while preserving quality of care within these programs. The Secretary must evaluate the quality of care, through measurement of patient-level outcomes and patient-centeredness criteria, furnished under each tested model.</p>	<p>CMI was established on November 16, 2010. As of March 1, 2012, the CMI has announced various care coordination demonstrations.<sup>20</sup></p>
<p><b>§ 3025</b> <b>Medicare Hospital Readmissions Reduction Program</b><sup>21</sup></p>	<p>Beginning with discharges on or after October 1, 2012, the Secretary of HHS must establish a hospital readmissions reductions program for potentially preventable readmissions covering three high volume or expenditure conditions (which will be expanded to include additional conditions in 2015). Under this program, components of Medicare's inpatient reimbursement will be reduced for acute care hospitals to account for excess readmissions resulting from the three applicable conditions.</p>	<p>CMS's final FY 2012 hospital inpatient payment rule establishes the program and identifies the three applicable conditions: acute myocardial infarction, heart failure, and pneumonia.<sup>22</sup></p>
<p><b>§ 3501</b> <b>Health Care Delivery System Research, Quality Improvement</b><sup>23</sup></p>	<p>Enables AHRQ's Director to establish the Center for Quality Improvement and Patient Safety for a number of purposes including identifying high quality and efficient providers, assessing research related to improving health care delivery, finding ways to translate such information rapidly and effectively, creating strategies for</p>	<p>None. PPACA authorized to be appropriated \$20 million to implement section 3501, however,</p>

<sup>19</sup> PPACA, §§ 3021, 10306, 124 Stat. at 389, 939.

<sup>20</sup> See [www.innovations.cms.gov](http://www.innovations.cms.gov) (last visited Mar. 15, 2012).

<sup>21</sup> PPACA, §§ 3025, 10309, 124 Stat. at 408, 942.

<sup>22</sup> *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment*, 76 Fed. Reg. 51476 (Aug. 18, 2011).

<sup>23</sup> PPACA, §§ 3501, 10501(f)(2), 124 Stat. at 507, 996.

	<p>quality improvement through the development of tools, methodologies, and interventions, and building capacity at the state and community level to lead quality and safety efforts through education, training and mentoring programs. The AHRQ Director must ensure that the Center's research findings are made publicly available and shared with the Office of the National Coordinator of Health Information Technology. The Center must also coordinate its activities with CMI.</p>	<p>to date, Congress has not appropriated any funds.</p>
<p><b>§ 4003</b> <b>Task Force on Clinical and Community Preventive Services<sup>24</sup></b></p>	<p>Reauthorizes the U.S. Preventive Services Task Force (USPSTF's) and provides explicit statutory authority for the existing Community Preventive Services Task Force (CPSTF).<sup>25</sup> The AHRQ Director is to convene and administer the USPSTF and the Director of the Centers for Disease Control and Prevention (CDC) is to convene the CPSTF. The USPSTF is charged with developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services. The CPSTF has similar responsibilities regarding the development of recommendations for community preventive services aimed at affecting health at the population level. Each Task Force must provide yearly reports to Congress regarding their work.</p>	<p>In July 2010, the USPSTF issued a list of preventive services with a rating of A or B. In 2011, each Task Force submitted their first annual reports to Congress.</p>

<sup>24</sup> PPACA, § 4003, 124 Stat. at 541.

<sup>25</sup> HHS first established the USPSTF in 1984 to develop recommendations for primary care clinicians on periodic health examinations. <http://odphp.osophs.dhhs.gov/pubs/guidecps/uspstf.htm>. HHS established the TFCPS in 1996 to develop guidance on community-based health promotion and disease prevention interventions. <http://www.thecommunityguide.org/about/history.html>

<b>§ 4301</b> <b>Research to Optimize Delivery of Public Health Services<sup>26</sup></b>	Directs the CDC to provide funding for research on public health services and systems, including examining evidence-based practices relating to prevention, analyzing the translation of interventions from academic to real world settings, and identifying effective strategies for organizing, financing, or delivering public health services. Research under this section is required to be coordinated with the TFCPS.	None.
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<sup>26</sup> PPACA, § 4301, 124 Stat. at 578.