

THE TSUNAMI OF HEALTH CARE RULEMAKING: STRATEGIES FOR SURVIVAL AND SUCCESS

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INTRODUCTION

In 2011–2015, health care regulation changes will present new challenges and opportunities to the novice lawyer in a general practice law office. Our purpose in this Article is to guide the novice at federal administrative rulemaking through the very challenging rulemaking aspects of implementing the Patient Protection and Affordable Care Act (PPACA or Act).¹ Even if you skipped the administrative law and health law courses in law school, your clients will ask for your help, and you can cheerily offer to guide them. Individuals, nonprofit groups, companies, doctors, pharmacies, hospitals, local governments, states, insurers, investment analysts, and product manufacturers are among the many types of law firm clients who will struggle with the implementation of the 2010 health care reform legislation. How well you perform in this rule-writing context may shape the future of your practice when more health law issues arise for your clients.

So much money is at stake for these clients that accurate advising and thoughtful preparation on Department of Health and Human Services

1. Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029. For purposes of this Article, “PPACA” refers to these bills collectively unless otherwise noted.

(HHS) rules could be essential to sustaining your role in those clients' profitable health care businesses. Rulemaking comments, well crafted and effectively supported by data, will be your future goal in serving these clients. Your sensitivity to federal and state motivations will result in more effective comments and meeting participation; the clients will benefit from your thoughtful preparatory work.

We confess that a guide to this massive law is impossible in these few short pages. We could try to parse its 406,887 words, slog through the 906-page PDF version from the Government Printing Office website, or even dance through the twelve-page table of contents for Public Laws 111-148 and 111-152, the basic statute and the companion "reconciliation" bill. Instead, in order to be both pragmatic and helpful, we will orient this Article toward aiding the novice in successfully drafting and submitting comments on the many agency rules that implement the new law's complex commands and constraints.

There is no question that PPACA will result in a tsunami of new administrative rulemaking. Although some of this important work has already begun and will be discussed below, there is still much more to come. This rulemaking will be contentious, pitting politicians, agency heads, insurers, industry lobbyists, health care consumer advocates, and individuals against each other in a monumental battle to shape the regulations that will ultimately define health care in America. By analogy, those health care participants who wander onto the PPACA beachfront unaware and unprepared for this particular tsunami could be overwhelmed by the roiling flood of red tape before they have a real opportunity to have any impact on the rulemaking process.

If the aphorism is correct that "the world is run by those who show up," the 2011 world of health care reform rulemaking is being run by a few dozen law firms and corporate lobbyists that represent major industries with financial stakes in the PPACA reforms.² They have equal free speech rights, but their sophistication in rulemaking can make them seem more equal than other smaller players.

This Article will target the needs of the small firm, solo, or public interest

2. See Kevin Bogardus, *Big Health Bucks Roll in for K St.*, THE HILL (Jan. 18, 2011, 7:00 AM), <http://thehill.com/business-a-lobbying/138387-big-health-bucks-roll-in-for-k-st> ("Since Jan. 1, close to a dozen firms and health care companies have hired new lobbyists and lawyers or have been formed to lobby on the new law's regulations, according to a review by The Hill."); Lindsay Renick Mayer, Michael Beckel & Aaron Kiersh, *Diagnosis: Reform* OPENSECRETSBLOG (June 17, 2009, 5:18 PM), <http://www.opensecrets.org/news/2009/06/diagnosis-reform.html>; *Health Care Tools*, OPENSECRET.S.ORG, http://www.opensecrets.org/capital_eye/health.php (last visited May 14, 2011) (listing contributions made by health-related industries to members of Congress).

attorney who advocates for the economic interests of citizens, patients, and less affluent players. We hope to provide you with the navigational tools you will need to have a say in this critical rulemaking that will define health care delivery and medical cost coverage for decades to come. This Article will also provide an overview of some of the most critical provisions in the legislation and an explanation of where the rulemaking on those segments will take us.

I. PREPARING FOR RULEMAKING

You may not recall the relevant segment of your law school administrative law course, but federal agency prospective policymaking, the process of rulemaking,³ comes in different flavors. Agencies use notice-and-comment rulemaking proceedings, guidance documents, informal letter interpretations, policy statements, interpretive rules, revenue rulings, interim final rules, direct final rules, and lots of tricks unfamiliar to the generalist attorney who rarely deals with agency rulemaking.⁴ Not all rules are alike, and some rules become final on different time scales than others. Final rules are effective with a thirty-day—or longer—lead time;⁵ some interim final rules are effective on the day they are published in the *Federal Register*, with an invitation for subsequent comments for a possible revision in the future.

Does the distinction make a difference? Yes. Jail terms, bans from federal contracts, and large civil penalties may be imposed based upon failure to follow a particular final rule. By contrast, all of the less formal, interpretive policy statements and the like do not bind private conduct and may be changed by the agency with no advance notice of the altered positions.

Timing really matters. The clock starts to run for a proposed rule's comment process⁶ when the proposed rule is published in the daily *Federal Register*.⁷ This is the day that may bring the client's phone call—"Help, I just learned that this proposed rule is intolerable/essential/expensive; what

3. 5 U.S.C. § 553 (2006).

4. See, e.g., FEDERAL ADMINISTRATIVE PROCEDURE SOURCEBOOK 2-5 (William F. Funk, Jeffrey S. Lubbers & Charles Pou, Jr., eds., 4th ed. 2008) (discussing the variants of formal and informal rulemaking under the Administrative Procedure Act (APA)); JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 3-7 (4th ed. 2006) (providing an overview of federal agency rulemaking after the passage of the APA).

5. 5 U.S.C. § 553(d).

6. *Id.* § 553(c).

7. 1 C.F.R. § 18.17(a) (2010) (noting that all documents submitted for publication in the *Federal Register* will include an effective date or time, either determined by the submitting agency or by the Office of the Federal Register).

do I need to do to track and comment on this proposal before the deadline?” Or the client might awaken late to the potential harm of a new proposal and may ask that you draft and file persuasive opposing comments by next Monday that will ask the agency to remove the worst aspects of the proposed rule.

For the hungry small-firm lawyer, this is a great opportunity. Find paying clients? Answer calls for legal services? Respond to complex government actions? There are several steps that you can take now to prepare. First, go to the website Regulations.gov and become familiar with its operations and its quirks.⁸ This will allow you to view each version of the proposed rule as it moves through rulemaking and submit your client’s comments on the proposals. Next, get a good book on rulemaking⁹ and learn the process for submission of comments¹⁰ and the means for tracking who is saying what on the Regulations.gov website. You will also need to expand your vocabulary and recognize that some actions of the HHS agencies under PPACA will be less than rules—they may be titled as informal guidances—and you have fewer opportunities to change these staff interpretations. By law, these policies do not bind the agency,¹¹ but on a daily basis, agency staffers use these to guide operations and make decisions that impact your clients.

After grounding yourself in the basics, seek to understand the agency’s process for presenting petitions for rulemaking¹² so that you will have the opportunity to express your client’s desired alternative. You will also need to study the ways in which the administrative record is set up for judicial review so that the rules which depend on that record are not later invalidated in court as arbitrary and capricious.¹³ And, perhaps the biggest challenge for most attorneys, you must learn to respond much more rapidly. Talk with your client about which issues you should monitor and which can be left to others for response.

In practical terms, this advice means that the client might hear that PPACA’s new rules on affordable care organizations, medical loss ratios (MLRs), funding of children’s health insurance program, and shared

8. REGULATIONS.GOV: YOUR VOICE IN FEDERAL DECISION-MAKING, <http://www.regulations.gov/> (last visited May 14, 2011).

9. See, e.g. LUBBERS, *supra* note 4 (intending to be used as a starting point for further research pertaining to agency rulemaking); JAMES T. O’REILLY, ADMINISTRATIVE RULEMAKING: STRUCTURING, OPPOSING, AND DEFENDING FEDERAL AGENCY REGULATIONS (2d ed. 2010).

10. 5 U.S.C. § 553(c).

11. *Id.* § 552(a)(2).

12. *Id.* § 555(e).

13. *Id.* § 706(2)(A).

Medicaid expense, etc., are being released for comment after many months of development inside the agency. When the proposed rules pop up in the daily *Federal Register*, your clients will have a very short time frame in which to assemble facts and arguments for the changes they want the agency to make in these rules.¹⁴ The best analogy is to tailoring a suit: the client may want your comments to ask for a longer timeline, a shorter payout period, an exception for the client's particular service or product, etc. This is where the lawyer who is a quick study can excel and help the client make those alterations so the rule is a better fit for the client's constituents.

The same legal skills are used for blocking a rule, changing its definitions, promoting its expansion, or winning an exception. The key is to add information to the agency's data set for the administrative record supporting your client's desired outcome. If, for example, your showing of a reason to change the proposed rule is accepted by the agency, the lengthy preamble to the final rule¹⁵ will note the reason behind the change from the rule first proposed. Your short-term task is to marshal a team who can assemble fact and policy arguments that support your client's desired outcome. Expertise for that team effort can be found within the client's organization, or hired from academia or the consulting universe. Proposals to change a rule should select the specific targeted section of the proposed rule, propose the alternative wording or novel alternative, and explain why your outcome meshes better with the statute than the staff's proposed rule. Attitudes matter; be persuasive by praising the agency's effort and by offering your option as an improvement that moves the agency's goals ahead faster, better, or less expensively. Do not refight battles lost in the legislative process.

II. PUBLIC INTEREST LAWYERS ARE AT A DISADVANTAGE

Rulemaking is a craft highly prized in some circles, but it is often overlooked in the legal aid office or other nonprofit entity that services retail client-by-client needs. Draining a regulatory swamp through rule changes is better than fighting each alligator individually in enforcement or penalty cases. Lawyers who work for the general public outside of government may feel intimidated by the stellar fame of lawyers representing entrenched entities, including many who eloquently resisted the PPACA

14. Another important resource is the website for the Office of the Federal Register Public Inspection Desk. See *Electronic Public Inspection Desk*, OFFICE OF THE FEDERAL REGISTER, <http://www.ofr.gov/inspection.aspx> (last visited May 14, 2011). Although the notices and proposed rules may be revised before publication in the *Federal Register*, this site can provide a few days' head start in your review of newly proposed rules.

15. 1 C.F.R. § 18.12 (2010).

changes.¹⁶ Do not neglect the reality that agency staff relates more to the public interest advocates' pleas than to the industrial contingent among the commenters.

The unusual public forum of federal agency rulemaking has its own style and machismo. Some say, "Why bother, the insiders will capture the agency rule despite our efforts?" But avoid defeatism: help your client be heard, and if the insider comments are filed before the closing deadline for comments, read those comments online and offer a different view. The insider's comments may be misleading or could be quite impractical at the operational level in ways your client will recognize but the agency may miss, so communicate the best counter argument to the agency.

For example, if your client is a local nonprofit charity hospital, you may notice that health insurers are using statistics. Watch out for the insurer's comments on the HHS rule that define terms such as "patient care." In PPACA, Congress placed controls on the profitability of health insurers, using the concept of MLRs to express what portion of the premiums paid could serve the insured and what portion could be spent for the owners and operators of the health insurance giants.¹⁷ PPACA attempted to place a 15% cap on the overhead cost of providing medical services.¹⁸ Astute insurance company lawyers began immediately to focus on the definition of what statistical categories patient care would include. To maximize their profitability and salaries in what ordinarily would be considered an overhead cost, the insurers sought a federal implementing rule counting the costs of taking all the health care quality measures as patient care expenditures. The protection of the insurers' profits would be optimized by a federal regulation allowing the insurers to load many expense items into the basket marked patient care. These cost items are moved into patient care categories, if the new rules permit, in order to allow a larger amount to be in the administrative overhead—and corporate profits—category of defined costs.

Rulemaking is the forum in which these tough issues are going to be fought. Lawyers, particularly those serving indigent patients, should be prepared to make effective, specific comments on partial aspects of these

16. For specifics on the resources expended by the health care and insurance industries to shape PPACA, see generally OpenSecrets.org. Of particular interest, see Mayer, *supra* note 2; *Health Care Tools*, OPENSECRETS.ORG, http://www.opensecrets.org/capital_eye/health.php (last visited May 14, 2011); *Tracking the Payback*, OPENSECRETS.ORG, <http://www.opensecrets.org/payback> (last visited May 14, 2011).

17. PPACA, Pub. L. No. 111-148, § 10,101(f), 124 Stat. 119, 885–87 (2010), *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1001(5), 124 Stat. 1030, 1030–32.

18. *Id.*

new rules. In terms of the economics of legal services, this rulemaking task is lopsided; a proposed rule could be a lucrative opportunity for law firms to build or retain profitable client hours. When paying clients see that they have a lot at stake, they are likely to authorize the lawyer to spend the time needed to craft, gain concurrence on, and submit a set of comments on the client's behalf. As a public interest lawyer, standing by in silence while a trade association or medical association "speaks for" your clients risks the loss of their opportunity to have their particular interests protected, since associations tend to homogenize the input of members into a politically palatable package. The lawyer's role in crafting PPACA implementation rules is both essential to a fair process and lucrative, for at least the health care- and insurance- sector advocates.¹⁹ And even for public interest lawyers, already stretched thin by the economic recession, this unbalanced game is still worth playing. Silent advocates would be drowned out by their opponents. Comments to future proposed rules intended to help indigent patients and the health care providers who care for them will be worth the effort expended.

III. WHAT RULES ARE COMING?

A. *Interim Final Rules*

Because effective dates for certain PPACA provisions occurred soon after it was enacted, HHS agencies had limited time to issue these implementing rules and did so by promulgating interim final rules, without allowing a comment period before implementation, instead providing a comment period following publication.²⁰ For example, on June 28, 2010, the Internal Revenue Service and the Employee Benefits Security Administration published a 196-page set of interim final rules and guidances in cooperation with the new federal Office of Consumer Information and Insurance Oversight (OCIIO).²¹ HHS formed the OCIIO to implement, monitor

19. See *Lobbying: Top Industries*, OPENSECRETS.ORG <http://www.opensecrets.org/lobby/top.php?indexType=i>, (ranking industries by their lobbying expenditures) (last visited May 14, 2011). In 2009 and 2010, pharmaceuticals/health products, insurance, hospitals/nursing homes, health professionals and health services/HMOs all ranked in the top twenty. *Id.*

20. Under the APA, interim final rulemaking occurs under the "good cause" exception to the more common notice-and-comment rulemaking process when the agency for good cause finds that notice-and-comment proceedings are "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B) (2006).

21. Requirements for Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections, 75 Fed. Reg. 37,188,

compliance with, and enforce the new rules governing the insurance market and the new rules regarding MLRs.²² In 2011, the OCIO became the Center for Consumer Information and Insurance Oversight (CCIO) and is a part of Centers for Medicare & Medicaid Services (CMS).²³

The interim final rules implement four provisions of PPACA. First, the rules raise the limits on benefit maximums by placing a ban on lifetime benefit caps (applicable for plan years beginning on or after September 23, 2010); a restriction on use of annual caps (applicable for plan years beginning on or after September 23, 2010); and a ban on annual caps (applicable for plan years beginning on or after January 1, 2014). Grandfathered individual policies are exempt.²⁴

For benefits that are not “essential health benefits,” a plan or issuer may impose annual or lifetime per-individual dollar limits on specific covered benefits.²⁵ The annual limits are to be phased in over three periods: (1) \$750,000 (applicable for plan years beginning September 23, 2010, or later); (2) \$1.25 million (applicable for plan years beginning September 23, 2011, or later); and (3) \$2 million (applicable for plan years beginning September 23, 2012, or later).

Anticipating that these new annual caps might result in the loss of coverage some employees receive under so called “mini-med” plans, the interim final regulations allow the Secretary of HHS to establish a program under which the requirements relating to restricted annual limits may be waived, if compliance with these interim final regulations would result in a significant decrease in access to benefits or a significant increase in

37,242 (June 28, 2010).

22. See OCIO Archived Site, U.S. DEP'T OF HEALTH AND HUMAN SERVS., <http://www.hhs.gov/ocio/about/index.html> (last visited May 14, 2011).

23. See 76 Fed. Reg. 4703 (Jan. 26, 2011).

24. See Requirements for Group Health Plans and Health Insurers under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 37,188, 37,223–25 (June 28, 2010) (prohibiting lifetime and annual limits, rescissions; requiring an appeals process, and prohibiting exclusions for preexisting conditions or other discrimination based on health status); See also PPACA, Pub. L. No. 111-148, §§ 1001, 1201, 2704, 2711, 2712, 2719A, 124 Stat. 119, 119, 131, 154, 887 (2010).

25. PPACA § 1302(b)(1) requires the Secretary of HHS to define “essential health benefits,” although it also sets out the minimum benefits that must be included: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; pediatric services including oral and vision care; and other services “typically covered by employers.” Also this section, the Secretary of Labor is required to conduct a survey of employer-sponsored coverage to determine what benefits are typically covered and report on that survey to the Secretary of HHS. PPACA § 1302(b)(2), 124 Stat. 119, 163.

premiums. HHS has promised additional guidance on this issue.²⁶

The second major area addressed by these interim final rules is the elimination of health insurers' exclusion of applicants because of preexisting conditions. The interim final rule prohibits group plans and individual issuers from imposing preexisting condition exclusions for enrollees under age nineteen for plan years beginning on or after September 23, 2010, and for all other enrollees beginning after January 1, 2014. These protections are in addition to the nondiscrimination provisions under the Health Insurance Portability and Accountability Act (HIPAA) that generally provide that group health plans and group health insurance issuers may not set eligibility rules based on factors such as health status and evidence of insurability, including acts of domestic violence or disability.²⁷

The third important area addressed under these interim final rules is a ban on the rescission of group health plans and individual health policies, except in cases involving fraud or intentional misrepresentation of a material fact, which became effective on September 23, 2010; only fifty comments were submitted on this interim final rule.²⁸

Among the other regulations adopted through interim final rulemaking, on May 5, 2010, CMS and HHS issued "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring and Documentation Requirements; and Changes in Provider Agreements."²⁹ This rule implements a number of provisions of PPACA, including: (1) § 6402(a), which requires all providers of medical or other items or services and suppliers under Titles XVIII (Medicare) and XIX (Medicaid) of the Social Security Act (SSA) that are eligible for a national provider identifier (NPI) to include the NPI on all applications to enroll in such programs, and on all claims for payment under such programs;³⁰ (2) § 6405(a) and (c), which indicate that orders and referrals for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) and for other categories of items and services that may be made by a physician or

26. Memorandum from Steven Larsen, Director, OCIO, *Insurance Standard Bulletin Series—INFORMATION* (Nov. 5, 2010), available at http://www.hhs.gov/ocio/regulations/11-05-2010annual_limits_waiver_bulletin.pdf.

27. See Health Insurance Portability and Accountability Act (HIPAA), 29 U.S.C. §§ 1181, 1182 (2006) (limiting exclusion of preexisting conditions and prohibiting discrimination based on health status).

28. See Comments on Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections, FR Doc #2010-15278, available at <http://www.regulations.gov/#!docketDetail;D=IRS-2010-0015> (last visited May 14, 2011).

29. 75 Fed. Reg. 24,437 (May 5, 2010) (to be codified at 42 C.F.R. pts. 424 & 431).

30. PPACA, § 6402(a), 124 Stat. at 753–64.

an “eligible professional under § 1848(k)(3)(B)” of the SSA;³¹ (3) § 6405(c), which gives the Secretary of HHS the discretion to determine the health professions that can order and refer items and services other than DMEPOS and home health³² (for example, companies that advertise “free” mobile wheelchairs will find their business practices questioned by HHS); and (4) section 6405(b), which, with respect to suppliers of durable medical equipment, provides that payment may be made under § 1834(a)(11)(B) of SSA only if the written order for the item has been communicated to the DMEPOS supplier by a physician who is enrolled in the programs.³³ These regulations, which are intended to help reduce the incidence of fraud, abuse, and waste in programs perceived to be high risk, became effective on July 6, 2010.³⁴ In the period between publication and effective date, only thirty-one entities submitted comments.³⁵

Also on May 5, 2010, HHS issued an interim final rule implementing PPACA § 1103(a),³⁶ which required HHS to establish a website for individuals and small businesses to obtain information about insurance coverage options available in their states.³⁷ The rule sets out the categories of information to be collected and displayed; the data that issuers must report; and the data that states, associations, and high-risk pools are requested to provide. This additional information will allow patients who use these new tools to be more selective.

HHS issued a third set of regulations on May 5, 2010, regarding the early retiree reinsurance program in order to implement PPACA § 1102.³⁸

31. *Id.* § 6405(a), (c), 124 Stat. at 768.

32. *Id.* § 6405(c), 124 Stat. at 768.

33. *Id.* § 6405(b), 124 Stat. at 768.

34. Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements, 75 Fed. Reg. 24,437, 24,437–38 (May 5, 2010) (to be codified at 42 C.F.R. pts. 424, 431).

35. The comments were from home health agencies and/or durable medical equipment suppliers. *See* Comments on Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and changes in provider agreements, FR Doc #2010-0817, available at, <http://www.regulations.gov/#!docketDetail;det=FR+PR+N+O+SR;rpp=10;D=CMS-2010-0187> (last visited May 14, 2011).

36. Health Care Reform Insurance Web Portal Requirements, 75 Fed. Reg. 24, 470, 24,470–71 (May 5, 2010) (to be codified at 45 C.F.R. pt. 159).

37. The website, [HealthCare.gov](http://www.healthcare.gov), was released by the July 1, 2010 deadline and now includes insurance comparisons, prevention information, links to the quality comparison website for hospitals, nursing homes, home health and dialysis facilities, and information on PPACA. *See* HEALTHCARE.GOV: TAKE HEALTH CARE INTO YOUR OWN HANDS, <http://www.healthcare.gov/> (last visited May 14, 2011).

38. Early Retiree Reinsurance Program, 75 Fed. Reg. 24,450, 24,451 (May 5, 2010) (to

§ 1102 requires HHS to reimburse sponsors with certified plans for a portion of the cost of health benefits for early retirees and their spouses or surviving spouses and dependents. Reimbursements will be “80 percent of the portion of the health benefit costs . . . attributable to the claims that exceed \$15,000, but are below \$90,000.”³⁹

Other interim final rules published in the early implementation include a rule implementing PPACA § 1001 for group health plans and health insurance coverage in the group and individual markets for dependent coverage of children who are not yet twenty-six, which became effective on July 12, 2010;⁴⁰ a rule required by PPACA § 10501(i) defining “underserved rural community” for purposes of the Rural Physician Training Grant Program, which became effective on June 25, 2010;⁴¹ a rule implementing PPACA § 1251 for group health plans and health insurance coverage in the group and individual markets for status as a “grandfathered” health plan, which became effective on June 14, 2010, with the exception of certain amendments that became effective on July 12, 2010;⁴² a rule implementing PPACA § 2713 regarding the requirements for group health plans and health insurance coverage in the group and individual markets, which became effective on September 17, 2010, and applies to group health plans and group health insurers for plan years beginning on or after September 23, 2010;⁴³ a rule implementing PPACA § 2719 regarding the requirements for internal claims and appeals and external review processes for group health plans and health insurance coverage in the group and individual

be codified at 45 C.F.R. pt. 149).

39. *Id.* at 24,456.

40. *See* Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Dependent Coverage of Children to Age 26 Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 27,122, 27,122–24 (May 4, 2010) (to be codified at 45 C.F.R. pts. 144, 146, & 147) (making dependent coverage available to children until age twenty-six).

41. *See* Public Health Service Act, Rural Physician Training Grant Program, Definition of “Underserved Rural Community,” 75 Fed. Reg. 29,447, 29,448–50 (May 26, 2010) (to be codified at 42 C.F.R. pt. 5a).

42. *See* Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 34,538, 34,538–40 (June 17, 2010) (to be codified at 45 C.F.R. pt. 147) (defining “grandfathered” plans as those existing at the date of enactment and only subject to certain provisions like the prohibition on rescissions).

43. *See* Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventative Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726, 41,726, 41,728 (July 19, 2010) (to be codified at 45 C.F.R. pt. 147) (including evidence-based items or services; immunizations for routine use; evidence-informed preventative care and screenings for infants, children, and adolescents; evidence-based preventative care and screenings for women).

markets, which became effective on September 21, 2010, and applies to group health plans and group health insurers for plan years beginning on or after September 23, 2010;⁴⁴ and a rule implementing PPACA § 1101 requiring HHS to establish a temporary high-risk insurance pool program to provide affordable health insurance coverage to uninsured individuals with preexisting conditions, which became effective September 30, 2010.⁴⁵

B. Rulemaking Still to Come

1. Medical Loss Ratio

Among the most hotly contested rulemakings under PPACA is likely to be the rule on health insurers' medical loss ratio. Compromises and sharp disagreements during the adoption of PPACA § 2715 led to an odd form of state–federal allocation of tasks.⁴⁶ Section 2715 directed the Secretary of HHS to consult with the National Association of Insurance Commissioners (NAIC) to develop standards for use by a group.⁴⁷ On October 27, 2010, the NAIC transmitted to federal agencies its uniform definitions and standard methodologies for MLRs as required under this section of PPACA.⁴⁸ HHS announced the regulation⁴⁹ and released it through the Office of the Federal Register Public Inspection Desk on November 22, 2010.⁵⁰ This unusual form of state–federal partnership in rulemaking might be criticized as an excessive delegation of executive powers to a state authority, but the President's health care negotiating team accepted the

44. See Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 43,330, 43,330–32 (July 23, 2010) (to be codified at 45 C.F.R. pt. 147) (requiring issuers to incorporate the internal claims and appeals processes and update in accordance with HHS's standards).

45. Pre-Existing Condition Insurance Plan Program, 75 Fed. Reg. 45,014, 45,014–15 (July 30, 2010) (to be codified at 45 C.F.R. pt. 152). The temporary high-risk health insurance pool program will continue until 2014 when state-based insurance exchange programs established under PPACA §§ 1311 and 1321 will be available. *Id.* at 45,014.

46. PPACA, Pub. L. No. 111-148, § 2715, 124 Stat. 119, 132–35 (2010).

47. *Id.*

48. Letter from Nat'l Ass'n of Ins. Comm'rs to Kathleen Sebelius, Sec'y, U.S. Dep't of Health & Human Servs. (Oct. 27, 2010), available at http://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf.

49. News Release, U.S. Dep't of Health & Human Servs., New Affordable Care Act Rules Give Consumers Better Value for Insurance Premiums (Nov. 22, 2010), <http://www.hhs.gov/news/press/2010pres/11/20101122a.html>.

50. Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 74,864 (Dec. 1, 2010) (to be codified at 45 C.F.R. pt. 158).

NAIC state officials' role in PPACA as part of legislative compromises.

Under PPACA § 2718(b), beginning on January 1, 2011, health insurance issuers in the individual, small group and large group markets have to pay rebates to their enrollees on a pro rata basis if the insurer's MLR in a plan year is less than the minimum ratio established under the law. For individual and small group markets, the MLR is 80%,⁵¹ HHS may adjust the percentage for a state if the Secretary determines the ratio may destabilize the individual market.⁵² For the large group market, the minimum MLR is 85%.⁵³ A state may have a higher MLR requirement and its own rebate program as long as it does not prevent an individual from applying to the federal program.⁵⁴

Under PPACA, the formula for calculating the MLR is: (reimbursement for clinical services + expenditures to improve health care quality) ÷ (total premium revenue – federal and state taxes and licensing or regulatory fees and accounting for risk adjustment, risk corridors, and reinsurance).⁵⁵ How the definitions are framed is one of the most controversial issues in the 2010 rulemaking.⁵⁶

PPACA requires the NAIC to establish uniform definitions and standardized methodologies for calculating the MLR.⁵⁷ On April 14, 2010, HHS, along with the Treasury and Labor Departments, issued a request for comments regarding PPACA § 2718.⁵⁸ The Departments outlined several specific areas for comment, and although inviting comments from all interested parties, they highlighted a special interest in comments from health insurance issuers and the states.⁵⁹

Recognizing its responsibility under PPACA, the NAIC adopted a transparent process to develop its definitions and standards.⁶⁰ This process

51. PPACA § 2718(b)(1)(A)(ii), 124 Stat. at 886.

52. *Id.* § 2718(b)(1)(A)(ii), (d), 124 Stat. at 886, 887.

53. *Id.* § 2718(b)(1)(A)(i), 124 Stat. at 886.

54. *Id.* (“or such higher percentage as a State may by regulation determine . . .”).

55. *Id.* § 2718(b)(1)(B)(i), 124 Stat. at 886.

56. See Arlene Weintraub, *Insurer Mounts Offensive And Defensive Strategies On Health Law*, KAISER HEALTH NEWS, Aug. 16, 2010, <http://www.kaiserhealthnews.org/Stories/2010/August/16/cigna-top-executives-response-to-health-law.aspx>.

57. PPACA § 2718(c), 124 Stat. at 887 (“Such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.”).

58. Medical Loss Ratios; Request for Comments Regarding Section 2718 of the Public Health Service Act, 75 Fed. Reg. 19,297, 19,298 (Apr. 14, 2010).

59. *Id.* at 19,299.

60. Letter from Jane Cline, President, Nat'l Ass'n of Ins. Comm'rs, & Therese M. Vaughan, Chief Exec. Officer, Nat'l Ass'n of Ins. Comm'rs, to Kathleen Sebelius, Sec'y, U.S. Dep't of Health & Human Servs. (June 1, 2010), *available at* http://www.naic.org/documents/committees_e_hrsi_hhs_response_mlr_100601.pdf (explaining that the NAIC

included holding open conference calls with NAIC subgroups; receiving letters from stakeholders; and posting all drafts, call summaries, and comment letters on the NAIC website.⁶¹ The NAIC also received ongoing input from congressional offices and HHS.⁶²

On August 17, 2010, the NAIC approved a proposed standard form for issuers to use when reporting their financial information to state regulators.⁶³ The revised form, now twenty-eight pages, assists state regulators in identifying and analyzing the MLR for comprehensive, major medical health insurance as required under PPACA § 2718.⁶⁴ On October 27, 2010, the NAIC transmitted its final MLR recommendations to HHS.⁶⁵ However, the NAIC continued to express concerns that the MLR requirements might have the unintended consequence of destabilizing insurance markets where consumer choice is limited.⁶⁶ The NAIC specifically requested that HHS give deference to the analysis and recommendations of state regulators on how the MLR requirements would be implemented in destabilized markets.⁶⁷

The OCIO published the MLR regulation as an interim final rule with request for comments that became effective on January 1, 2011. Whether the concerns of the NAIC—that strict interpretation and enforcement will result in a destabilized market—are well-taken remains to be seen. However, in reaction to the MLR, employers who provide very low coverage policies to their low-wage workers have also expressed concern that these limits might result in low-wage workers losing their coverage entirely until mandatory coverage provisions become effective in 2014.⁶⁸ Under such plans, employees may pay as little as \$14 per week for a mini-med plan that caps annual benefits at \$2,000 per year or about \$32 per

hosted twelve conference calls and received over fifty comments when developing its definitions and standards).

61. *Id.*

62. *Id.*

63. News Release, Nat'l Ass'n of Ins. Comm'rs, NAIC Approves Form for MLR Financial Reporting Requirements (Aug. 17, 2010), http://www.naic.org/Releases/2010_docs/naic_approves_mlr_reporting_form.htm.

64. NAT'L ASS'N OF INS. COMM'RS, *Medical Loss Ratio (MLR) Blanks Proposal 1* (June 18, 2010), available at http://www.naic.org/documents/index_health_reform_mlr_blanks_proposal.pdf.

65. Letter from Nat'l Ass'n of Ins. Comm'rs to Kathleen Sebelius, Sec'y, U.S. Dep't of Health & Human Servs. (Oct. 27, 2010), available at http://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf.

66. *Id.*

67. *Id.*

68. See Janet Adamy, *McDonald's May Drop Health Plan*, WALL ST. J., Sept. 30, 2010, at A1.

week for coverage up to \$10,000 per year.⁶⁹ According to the *Wall Street Journal*, McDonald's, which offers mini-med plans for its workers at 10,500 U.S. locations, expressed concern to HHS that its insurer will not meet the 2011 requirement to spend at least 80–85% of its premium revenue on medical care.⁷⁰ Although McDonald's later issued a statement denying that it had expressed concerns about its ability to continue providing mini-med plan coverage to its employees,⁷¹ it seems almost certain that such issues might arise for at least some employers relying on these plans to cover their employees.

2. Health Information Technology

On November 3, 2010, the OCIIO and CMS issued guidance and a notice of proposed rulemaking to provide federal direction and financial support to help states develop consumer-oriented information technology (IT) systems to implement key coverage provisions of PPACA.⁷² The guidance relates to IT systems that states would establish to enroll people who qualify for Medicaid, the Children's Health Insurance Program (CHIP), tax credits, or cost-sharing reductions available under PPACA.⁷³ HHS also announced new federal funding that will be available to all states to streamline and upgrade their Medicaid eligibility systems.⁷⁴ The HHS announcement follows the OCIIO's October 29, 2010 release of the Funding Opportunity Announcement (FOA) for the design and implementation of the information technology infrastructure needed to operate health insurance exchanges.⁷⁵

69. *Id.*

70. *Id.*

71. Media Statement, Steve Russell, Senior Vice President & Chief People Officer, McDonald's USA, *Response to WSJ Health Care Article*, http://www.aboutmcdonalds.com/mcd/media_center/recent_news/media_press_releases/response_to_wsj_health_care_article.html (last visited May 14, 2011).

72. Notice from Joel Ario, Dir., Office of Consumer Info. & Ins. Oversight, and Cindy Mann, CMS Deputy Admin. and Dir., Ctr. for Medicare & Medicaid Servs., to State Medicaid Dir.s., Health Officials, and Health Ins. Comm'rs. (Nov. 3, 2010), *available at* http://www.healthcare.gov/center/letters/improved_it_sys.pdf.

73. *Health Insurance Exchanges Information Technology*, DEP'T OF HEALTH & HUMAN SERVS., http://www.hhs.gov/ociio/regulations/health_insurance_exchange_info_tech_sys.html (last visited May 14, 2011).

74. Press Release, Dep't of Health & Human Servs., HHS Announces New Federal Support or States to Develop and Upgrade Medicaid IT Systems and Systems for Enrollment in State Exchanges (Nov. 3, 2010), <http://www.hhs.gov/news/press/2010pres/11/20101103a.html>.

75. Under PPACA § 1561, HHS, in consultation with the Health Information Technology (HIT) Policy Committee and the HIT Standards Committee, must develop

IV. FRAUD AND ABUSE ISSUES

PPACA made major changes in an effort to prevent Medicare and Medicaid fraud and abuse. As discussed below, the rules implementing the fraud and abuse enhancements focus on tightening the regulations for known high-risk industries and services, clarifying intent requirements and when suspension of payments can occur, enhancing screening requirements, and mandating compliance programs.

A. Disclosure Requirements for In-Office Ancillary Services Exception

PPACA mandates that HHS adopt regulations⁷⁶ requiring that with respect to magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), and any other designated health services (DHS) deemed appropriate by the Secretary, the referring physician must notify the patient in writing at the time of the referral of other suppliers “who furnish such services in the area in which [the patient] resides.”⁷⁷ The term *other designated health services* was defined under this section to include any DHS set out at 42 U.S.C. § 1395nn(h)(6)(D) that HHS “determines appropriate.”⁷⁸ Although the SSA includes a broad definition of DHS,⁷⁹ the final rule limits the referral notices to only those included in the PPACA text: MRIs, CTs, and PET scans.⁸⁰ The final rule also reduces the number of suppliers required to be listed from ten in the proposed rule to five in the final; eliminates the requirement that the supplier’s distance from the physician’s office be listed on the disclosure

interoperable, secure standards and protocols that facilitate electronic enrollment of individuals in federal and state health and human services programs. See *Electronic Eligibility & Enrollment*, OFFICE OF THE NAT’L COORDINATOR FOR HEALTH INFO. TECH., <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3161> (last visited May 14, 2011) (adopting the Policy and Standards Committees’ recommendations, with slight edits, on September 17, 2010).

76. PPACA, Pub. L. No. 111-148, § 6003, 124 Stat. 119, 697 (2010).

77. *Id.* § 6003(a), 124 Stat. at 697.

78. *Id.*

79. The term “designated health services” means any of the following items or services: (A) clinical laboratory services, (B) physical therapy services, (C) occupational therapy services, (D) radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services, (E) radiation therapy services and supplies, (F) durable medical equipment and supplies, (G) parenteral and enteral nutrients, equipment, and supplies, (H) prosthetics, orthotics, and prosthetic devices and supplies, (I) home health services, (J) outpatient prescription drugs, and (K) inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6) (2006).

80. Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73,170, 73,616 (Nov. 29, 2010) (to be codified at 42 C.F.R. § 411.355(b)(7)(i)).

notice; and eliminates the requirement that the physician obtain the patient's signature on the notice and retain a copy of the disclosure as part of the patient's medical record.⁸¹ These changes from the proposed to final rule were based on comments received in response to the proposed rule.⁸²

This requirement was said to be "effective" for services provided on or after January 1, 2010.⁸³ However, in the final rule, CMS moved the effective date to January 1, 2011.⁸⁴

B. Compliance Program Requirements

One of the most significant fraud and abuse requirements under PPACA is that all providers and suppliers who enroll with Medicare must adopt compliance plans as a condition of enrollment.⁸⁵ The statute requires that HHS, in consultation with the Office of the Inspector General (OIG), must adopt core elements of compliance plans for each type of provider or supplier, and for each industry segment.⁸⁶ It seems likely that HHS will adopt core elements based on the compliance guidance documents previously published by the OIG.⁸⁷ PPACA § 6401(b)(5) contains a similar requirement for providers and suppliers under Medicaid.⁸⁸

Because states will have an important role in the implementation of compliance plans within the sphere of state Medicaid programs, counsel should also be aware of whether or not their state has adopted (or is in the process of adopting) compliance program requirements for participation in the Medicaid program.⁸⁹

C. Medicaid Recovery Audit Contractors

In addition to the preventative measures of requiring Medicaid compliance programs, PPACA also requires more aggressive audit protocols. PPACA § 6411 requires the states to establish programs in which they would contract with one or more Recovery Audit Contractors

81. *Id.*

82. *See id.* at 73,443–47.

83. PPACA § 6003(b), 124 Stat. at 697.

84. Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. at 73,447.

85. PPACA § 6401(a)(7), 124 Stat. at 751.

86. *Id.*

87. For links to the OIG's previously published guidance documents, see *Compliance Guidance*, OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVICES, <http://oig.hhs.gov/fraud/complianceguidance.asp> (last visited May 14, 2011).

88. PPACA § 6401(b)(5), 124 Stat. at 752.

89. *See, e.g.*, 18 N.Y.C.R.R. § 521.1 (2009) (listing New York State's Medicaid provider compliance program requirements).

(Medicaid RACs) by December 31, 2010.⁹⁰ The Medicaid RACs would review Medicaid claims submitted by providers of services for which payment may be made under § 1902(a) of the SSA or a waiver of the state plan.⁹¹ Medicaid RACs would both identify underpayments and identify and collect overpayments from providers.

On November 10, 2010, CMS issued proposed rules to provide guidance related to federal–state funding of state start-up, operation and maintenance costs of Medicaid RACs, and payment methodology for state payments to Medicaid RACs.⁹² The rule also proposes requirements for states to assure that adequate appeal processes are in place for providers to dispute adverse determinations made by Medicaid RACs.⁹³ Further, the rule “proposes that states and Medicaid RACs coordinate with other contractors and entities auditing Medicaid providers as well as with state and federal law enforcement agencies.”⁹⁴ The proposed rules allowed sixty days for comments.⁹⁵

There are a number of areas for concern while the rulemaking is underway. Because Medicaid RACs will be managed at the state level, providers must be aware that the appeal processes may well be different from state to state. Because the stated goal of the Medicaid RAC program is to cut overpayments in half by 2012,⁹⁶ Medicaid providers should expect aggressive audit protocols. Medicaid RAC payments are limited to a 12.5% contingency fee, although states can pay more if they pay the excess fee on their own.⁹⁷ This contingency fee arrangement will provide a powerful incentive for Medicaid RACs to identify overpayments. States are already seeking exemptions. On November 8, 2010, the South Dakota Department of Social Services published a notice that it was proposing amendments to South Dakota’s Medicaid State Plan effective October 1, 2010, and seeking an exemption from the Medicaid RAC requirements under PPACA § 6411.⁹⁸

90. PPACA § 6411(a)(1), 124 Stat. at 774–75.

91. *Id.*

92. Medicaid Program; Recovery Audit Contractors, 75 Fed. Reg. 69,037 (Nov. 10, 2010) (to be codified at 42 C.F.R. pt. 455).

93. *Id.* at 69,037–38.

94. *Id.* at 69,038.

95. *Id.* (requiring all comments be received by January 10, 2011).

96. In 2009, the Center for Medicare and Medicaid Services (CMS) identified \$18.6 billion in improper Medicaid payments. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-09-628T, IMPROPER PAYMENTS: PROGRESS MADE BUT CHALLENGES REMAIN IN ESTIMATING AND REDUCING IMPROPER PAYMENTS 5 (2009), available at <http://www.gao.gov/new.items/d09628t.pdf>.

97. Medicaid Program; Recovery Audit Contractors, 75 Fed. Reg. at 69,039.

98. See 37 S.D. Reg. 99, 99 (Nov. 8, 2010), available at <http://legis.state.sd.us/rules/>

D. Suspension of Payments Upon Allegation of Fraud

Although current regulations allow HHS to place a provider's prepayment claims under review or to impose a suspension of payment under certain circumstances, PPACA § 6402(a) expands HHS's authority with regard to the circumstances when suspension can be initiated. On September 23, 2010, CMS issued proposed rules on suspension.⁹⁹ A final rule was published on February 2, 2011.¹⁰⁰ Under the previous rules, a suspension of payments was limited to 180 days unless it met one of several exceptions.¹⁰¹ A Medicare contractor could request a one-time-only extension for up to an additional 180 days if it was unable to complete its investigation within the first 180-day period.¹⁰² The OIG or other law enforcement agency could also request a one-time-only exception in order to complete an investigation.¹⁰³ Under the final rule, the time limits do not apply if the case has been referred to, and is being considered by the OIG for administrative action; the rule would also permit HHS to grant an extension beyond the 180-day extension if the Department of Justice (DOJ) requests the continued suspension of payments based on the ongoing investigation and anticipated filing of criminal or civil actions.¹⁰⁴

CMS is permitted to suspend payments to a supplier or provider where there is a "credible allegation" of fraud.¹⁰⁵ Under the final rule, a credible allegation can include an allegation from any source, including but not limited to fraud hotline complaints, claims data mining, patterns identified through provider audits, civil false claims cases, and law enforcement investigations.¹⁰⁶ Allegations will be considered credible when they have "indicia of reliability."¹⁰⁷ CMS concedes that this will need to be

register/11082010.pdf (seeking to revise the state Medicaid plan pursuant to PPACA).

99. Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 75 Fed. Reg. 58,204 (Sept. 23, 2010) (to be codified at 42 C.F.R. pts. 405, 424, 438, 447, 455, 457, 498, 1007).

100. Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. 5862 (Feb. 2, 2011) (to be codified at 42 C.F.R. pts. 405, 424, 447).

101. 42 C.F.R. § 405.372(d) (2009).

102. *Id.*

103. *Id.*

104. *Id.*; 42 C.F.R. §§ 405.370–79 (2010).

105. Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. at 5961.

106. *Id.*

107. *Id.*

determined on a case-by-case basis.¹⁰⁸

Under PPACA, the CMS is permitted to suspend payments to a supplier or provider pending an investigation of a credible allegation of fraud.¹⁰⁹ Counsel who are representing smaller suppliers or providers know that any interruption in the Medicare revenue stream can cause significant hardship for the client. An indefinite length of payment suspension pending the outcome of an investigation might well put many of these entities out of business. Where overpayments are characterized as having been obtained through fraud, the overpayment debt will not be dischargeable in bankruptcy.¹¹⁰ The HHS decision on when and how to suspend has due process implications, and opposition to the final rule could be taken to the appeals court either as a rulemaking challenge or as a defense to an HHS adjudicative decision upholding the suspension of a particular provider who then sues to invalidate the program on constitutional grounds. Although CMS received “numerous comments raising concern over the perceived lack of due process afforded to the provider community,” it declined to “withdraw the suspension provision from the final rule with comment period” because the agency believed “the due process protections are more than adequate and the evidentiary standards for payment suspensions cannot be more precisely defined.”¹¹¹

E. Medicare Self-Referral Disclosure Protocol

PPACA requires the Secretary to implement regulations establishing a self-disclosure protocol,¹¹² specifically for hospitals or other providers who have found violations of the Stark (anti-kickback) provisions of the Medicare statute.¹¹³ Under the previous self-referral disclosure protocol, the large strict liability burden was relieved if the provider told the government about its past violation before the government found out about the violation. This allowed a hospital that found such a bad program when it merged with another hospital to inform the government, stop the bad conduct, and avoid severe penalties. But before the passage of PPACA, on March 24, 2009, the OIG announced that it had ceased accepting medical entities’ self-disclosure of Stark violations under its self-disclosure

108. *Id.* at 5966 (to be codified at 42 C.F.R. § 455.2).

109. PPACA, Pub. L. 111-148, § 6402(a), 124 Stat. 119, 760 (2010).

110. *See* 11 U.S.C. § 523(a)(2)(A) (2006).

111. Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. at 5930–31 (to be codified in 42 C.F.R. pts. 405, 424, 447, 455, 457, 498, 1007).

112. PPACA § 6409, 124 Stat. at 772.

113. *See generally* 24 U.S.C. § 1395nn (2006).

protocol.¹¹⁴ PPACA reinstates a form of safe harbor and possible reduction of amounts owed for those who report their situations before being detected and punished.¹¹⁵ Safe harbor provisions to shield a provider from strict liability under the Stark statute¹¹⁶ are perceived to be so important that the lobbyists for health care companies pressed Congress to reinstate their ability to “confess” their noncompliance.

On September 23, 2010, CMS issued its Voluntary Self-Referral Disclosure Protocol (SRDP).¹¹⁷ And, while providers and their advocates might have hoped for an opportunity to comment on the SRDP, CMS issued the SRDP without using notice-and-comment rulemaking. Additionally, while PPACA authorizes HHS to “reduce the amount due and owing” to these violations,¹¹⁸ the SRDP makes it clear that CMS “has no obligation to reduce any amounts due and owing” and will make an “individual determination as to whether a reduction is appropriate.”¹¹⁹

F. Nursing Homes

PPACA has significant impacts on long-term care institutions such as nursing homes. As is the case with other high-visibility spending programs, rules implementing the new statute will be controversial with many competing constituencies.¹²⁰ In particular, a number of PPACA provisions will have long-ranging impacts on the safety of patients in long-term care facilities.

Under PPACA § 6103, HHS must add to the Nursing Home Compare

114. Press Release, Daniel R. Levinson, Inspector Gen., U.S. Dept. of Health & Human Servs, An Open Letter to Health Care Providers (Mar. 24, 2009), available at <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>.

115. PPACA § 6409(b), 124 Stat. at 772–73.

116. 24 U.S.C. § 1395nn(g).

117. DEP’T. HEALTH & HUMAN SERVS., OMB 0938-1106, CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL (Sept. 23, 2010), https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

118. PPACA § 6409(b), 124 Stat. at 772–773.

119. *Supra* note 117, § VIII.

120. Medicare expenditures for Nursing Care Facilities and Continuing Care Retirement Communities exceeded \$27,991 million in 2009, excluding the federal share of Medicaid costs. *National Health Expenditures by type of service and source of funds, CY 1960–2009*, CENTERS FOR MEDICARE AND MEDICARE SERVS., https://www.cms.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage (last visited May 14, 2011). Compared to Medicare expenditures in 2009 for home health care (\$29,835 million) and durable medical equipment (DME) (\$7445 million). *Id.* Both home health and DME were targeted under PPACA for additional fraud prevention requirements. See PPACA § 6407, 124 Stat. at 769–70.

website¹²¹ information including: staffing data, including staffing turnover and tenure; links to state Internet websites with information regarding state survey and certification programs; links to Form 2567 state inspection reports (deficiency reports); guidance for consumers on how to interpret and understand deficiency reports; and the facility plan of correction or other response to such reports; a standardized complaint form; summary information on the number, type, severity, and outcome of substantiated complaints; and the number of adjudicated instances of criminal violations by a facility or its employees that were committed in the facility, including those that involve abuse, neglect, exploitation, “or other violations or crimes that resulted in serious bodily injury.”¹²² The information must be presented “in a manner that is prominent, updated on a timely basis, easily accessible, readily understandable to consumers of long-term care services, and searchable.”¹²³ This information could be indicative of safety issues within the facility.

Under PPACA § 6105, by March 2011, HHS must develop a standardized complaint form that residents or persons acting on their behalf may use to file a complaint with a state survey agency or long-term care ombudsman program. Further, states must establish a complaint resolution process that includes: procedures to assure accurate tracking of complaints; procedures to determine the severity of complaints; procedures for complaint investigations; and deadlines for responding to complaints. In addition to the standardized form, complaints may still be submitted in other ways and formats, including orally.¹²⁴

The health reform bill also requires HHS, by December 31, 2011, to establish and implement a quality assurance and performance improvement program (QAPI program) for skilled nursing facilities and nursing facilities,¹²⁵ including multiunit chains of facilities.¹²⁶ Under the QAPI program, HHS must “establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best

121. See *Nursing Home Compare*, MEDICARE.GOV, <http://www.medicare.gov/NHCompare/> (last visited May 14, 2011).

122. PPACA § 6103(a)(1)(B), 124 Stat. at 704.

123. *Id.*

124. *Id.* § 6105(a), 124 Stat. at 711–12.

125. Generally, skilled nursing involves physical, speech, occupational, or other therapy services and is typically reimbursed by Medicare. Nursing facilities are more custodial and are reimbursed under Medicaid programs. See 42 U.S.C. § 1395i-3(a) (2006) (defining *skilled nursing facility*); *Id.* § 1396r(a) (2006) (defining *nursing facility*).

126. PPACA § 6102, 124 Stat. at 702–04.

practices in order to meet such standards.”¹²⁷ One year after the regulations are promulgated, “a facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities.”¹²⁸

Under PPACA § 6201, HHS must establish a nationwide program “to identify efficient, effective, and economical procedures”¹²⁹ for background checks of workers with direct patient access, modeled on the pilot program conducted under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.¹³⁰ The procedures must include search of state-based abuse and neglect registries and state and federal criminal history records, as well as a fingerprint check.¹³¹ States must conduct the screening and criminal history background checks under the nationwide program;¹³² monitor compliance by long-term care facilities and providers;¹³³ provide for provisional employment, up to sixty days, for employees and for direct on-site supervision for employees pending completion of an appeal process;¹³⁴ provide for an independent process by which a provisional employee or employee may appeal or dispute the accuracy of information;¹³⁵ and provide for a single state agency to be responsible for overseeing the process (including specifying the disqualifying offenses).¹³⁶ The OIG must evaluate the nationwide program and submit a report to Congress.¹³⁷

PPACA § 2043 provides grants and training to the ombudsman program to identify cases of abuse and neglect.¹³⁸ HHS will make the grants to eligible entities with relevant expertise and experience in abuse and neglect in long-term care facilities or long-term care ombudsman programs and responsibilities to: improve the capacity of state long-term care ombudsman programs to respond to and resolve complaints about abuse and neglect; conduct pilot programs with state long-term care ombudsman offices or local ombudsman entities; and provide support for such state long-term care ombudsman programs and pilot programs (such as through the

127. *Id.*

128. *Id.*

129. *Id.* § 6201(a), 124 Stat. at 721–27.

130. Pub. L. 108-173, § 307(a), 117 Stat. 2066, 2257.

131. PPACA § 6201(a)(3), 124 Stat. at 722.

132. *Id.* § 6201(a)(4)(B)(i), 124 Stat. at 723.

133. *Id.* § 6201(a)(4)(B)(ii), 124 Stat. at 723.

134. *Id.* § 6201(a)(4)(B)(iii), 124 Stat. at 723.

135. *Id.* § 6201(a)(4)(B)(iv), 124 Stat. at 723.

136. *Id.* § 6201(a)(4)(B)(v), 124 Stat. at 723.

137. *Id.* § 6201(a)(7)(B), 124 Stat. at 726–27.

138. *Id.* §§ 2043, 6703(a)(1)(C), 124 Stat. at 304–05, 782–85.

establishment of a national long-term care ombudsman resource center).¹³⁹

So, for attorneys with clients who are residents in or the owners of the long-term care industry, it is going to be vitally important to stay alert for proposed rules and to move as quickly as possible. Those who passively rely on trade groups to take the lead in commenting on proposed rules may be doing a disservice to their clients and to their own bottom line.

G. Drug Manufacturers

How much are the drugs used by seniors on Medicare going to cost? Federal pricing figures for reimbursement of drugs are a twisted jumble of competing discounts and baseline numbers, with serious negative consequences for those who charge the government too much relative to other purchasers. On September 3, 2010, CMS issued a proposed rule withdrawing the prior CMS regulations governing the determination of average manufacturer price, the definition of multiple source drugs, and the application of federal upper reimbursement limits for multiple source drugs (the proposed rule).¹⁴⁰ This withdrawal would impact the applicable regulations finalized by CMS in 2007¹⁴¹ and 2008¹⁴² but would leave intact other sections of the 2007 regulations, including, for example, the best price provisions and certain definitions (including the definition of “bona fide service fee”). Comments were filed before October 4, 2010.¹⁴³ When states, insurance firms, and drugmakers comment on the impact of the withdrawn regulations, they also comment upon the open issues in accounting for wholesale drug pricing that have not been addressed under PPACA.

V. WHEN ARE ALL OF THE RULES COMING?

Prudent counsel will buy a very big calendar and fill in many of the statutory deadlines. Time pressures on publication of regulations within the tight 180- and 360-day deadlines in this 2010 legislation will force the federal agencies to get their first set of rules in place quickly, and will press

139. *Id.*

140. Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs, 75 Fed. Reg. 54,073, 54,075 (proposed Sept. 3, 2010) (to be codified at 42 C.F.R. pt. 447).

141. Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,142 (July 17, 2007) (codified at 42 C.F.R. pt. 447).

142. Medicaid Program; Multiple Source Drug Definition 73 Fed. Reg. 58,491 (Oct. 7, 2008) (to be codified at 42 C.F.R. pt. 447).

143. Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs, at 54,073.

state Medicaid advisors and state legal officers to bring their health insurance risk pools and exchanges into rapid operation.¹⁴⁴ News media, congressional committees, and affected constituency groups can be expected to publicize “excessive” delays in rulemaking by the agency, so act quickly; the chances for an affected entity receiving a lengthy extension on the comment period are not great. Again, silence is deemed assent.

The rule drafting clock began running as soon as PPACA was enacted in early 2010, and compliance deadlines will sneak up on less-prepared clients. Time pressures on the attorney will arise from the phenomenon that some health care law participants are slowly awakening to impacts that they had not realized. For example, assume that an attorney works for a state health agency, and that the state’s governor returns from a National Governors Association meeting to ask the staff, “What’s up with this topic; they tell me our comments must be filed by x date?” This should have been anticipated. Counsel should monitor the legal publisher services for timelines and time charts on new health care regulations. State employee attorneys should be prepared to predict what this proposed rule might do to the state budget. Their formula for success may be to write a strong draft, make the governor look terrific in responding and leading the charge, and win an accommodation in the final rule that shows victory for the governor’s viewpoint—their careers will flourish!

VI. WHAT HAPPENS IF I DO NOTHING?

Advocates for reform cannot declare victory in Congress and go home. Rulemaking is just as crucial a challenge as lawmaking. Another consideration for lawyers who file comments representing public sector clients is the tremendous political and legal backlash caused by PPACA’s passage. Efforts by the new Republican majority in the House of Representatives to repeal PPACA, though blocked by the Democratic Senate, are likely to have some trickle-down pressures upon the HHS rulemaking process, with the Administration accommodating some of the criticisms by modifying the rules to meet opponents halfway. Still another consideration is a series of ongoing court challenges to the constitutionality of PPACA itself. Most of these lawsuits have been dismissed by federal district courts, but federal judges in two cases filed by states ruled portions

144. See, e.g., PPACA § 1001, 124 Stat. at 130–38 (not later than two years); § 6001, 124 Stat. at 684–89 (before July 1, 2011); § 6102, 124 Stat. at 702–04 (not later than December 31, 2011 for some provisions); § 7102, 124 Stat. at 823–27 (not later than 180 days after enactment); § 8002, 124 Stat. at 828–47 (not later than October 1, 2012); PPACA § 10101, 124 Stat. at 883–91 (not later than December 31, 2010); § 10201, 124 Stat. at 917–24 (not later than 180 days after enactment of subsection).

of PPACA unconstitutional.¹⁴⁵

VII. LAWYERS, CLIENTS, AND MONEY

PPACA will be an especially important source of income for the health care practice groups of the nation's largest law firms. In 2009–2010, the debates over passage of the several health care reform bills were massively lucrative for lobbyists. Cynics may say that it is now up to the advocates who fight in opposition to health law rules to amass their own profits as they bill the health-related companies who have the greatest amount of financial skin in the game on the outcome of rule drafting and rule review.¹⁴⁶

We can anticipate that the quality of rulemaking comments produced by the health care companies and associations will be quite impressive, since they have more resources to collect and present data on what rules would cost. By contrast, advocates for patients and taxpayers may have less access to numbers, and therefore a variable quantity and quality of data to add to the agency's rulemaking record. Employers will sometimes allow their associations to collectively present aggregate statistics for their industry. Public interest advocates should match up what these advocates are saying with the public statements that their clients made during the legislative process. The inconsistencies should be noted in the record and in press coverage of the comments filed.

145. Compare *Florida ex rel. Bondi v. Dep't. of Health & Human Servs.*, No. 3:10-CV-91-RV/EMT, 2011 WL 285683 (N.D. Fla. Jan. 31, 2011), clarified by No. 3:10-CV-91-RV/EMT, 2011 WL 723117, at *1 (N.D. Fla. Mar. 3, 2011) (holding the individual mandate to purchase health insurance in PPACA to be in violation of the Commerce Clause, and declaring the whole act unconstitutional because the individual mandate is not severable from the remainder of the act), and *Virginia ex rel. Cuccinelli v. Sebelius*, 728 F. Supp. 2d 768, 790 (E.D. Va. 2010) (holding the individual mandate in violation of the Commerce Clause, but holding that provision severable from the rest of PPACA) with *Liberty Univ. v. Geithner*, No. 6:10-CV-00015-NKM, 2010 WL 4860299, at *31 (W.D. Va. Nov. 30, 2010) (holding that PPACA did not violate Commerce Clause, Free Exercise Clause, Free Speech Clause, or equal protection rights of individuals), and *Thomas More Law Ctr. v. Obama*, 720 F. Supp. 2d 882, 895–96 (E.D. Mich. 2010) (holding the individual mandate permissible under the Commerce Clause).

146. See, e.g., Bogardus, *supra* note 2 (“Since Jan. 1, close to a dozen firms and health care companies have hired new lobbyists and lawyers or have been formed to lobby on the new law’s regulations, according to a review by *The Hill*.”); Mayer, *supra* note 2; see also *Health Care Tools*, OPENSECRETS.ORG, *supra* note 2; *Tracking the Payback*, OPENSECRETS.ORG, *supra* note 2.

VIII. MAKING A SUCCESSFUL COMMENT

The content of a substantive comment to a federal agency will be crucial. The goal is to have one's presentation carefully read by the decisionmakers inside the agency.¹⁴⁷ The agency staff will have already spent many days researching their draft rules. The value of each public interest comment to them is enhanced by the quality of data and utilization information that health officials and hospital providers have supplied to their community's comment writers. Rhetorical flourishes do not win rulemaking disputes; to win on the expected judicial appeals, the administrative record must be supported by statistics and reliable sources. Public sector and nonprofit sector commenters need to anticipate the impact of this disparity between them and the health insurance industry. Public interest advocates should keep the agency staff aware of the effects of PPACA on poor and underserved populations.

IX. THE TOBACCO MODEL

The best comparative experience with which to study this health care rulemaking may be the massive tobacco rulemaking of the 1990s, one of the largest rulemaking projects in recent history. Years of effort by the Food and Drug Administration (FDA) led to a massive final rule,¹⁴⁸ which the Supreme Court killed by a 5–4 vote in March 2000.¹⁴⁹ The tobacco experience taught the health insurance companies how to be effective in shaping the administrative record against proposed rules. This is a valid comparison, because the two groups have hired similar advisors, similar law firms, and have used similar tactics. Many millions of dollars were spent on lobbying during the statutory phase of health care reform; millions will be spent during rulemaking phases.¹⁵⁰ An instructive comparison is the 2008

147. For some rules on which very large numbers of comments are expected, an outside law firm or federal contractor may screen every page and seek commonality. See JAMES O'REILLY, ADMINISTRATIVE RULEMAKING § 6:10 (2d ed. 2010).

148. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996) (codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897) (the final rule totaling 1,188 pages).

149. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121–26 (2000) (finding Congress “clearly precluded the FDA from asserting jurisdiction to regulate tobacco products”).

150. See Jennifer Liberto, *Health care lobbying boom continues*, CNNMONEY.COM, Mar. 25, 2011, http://money.cnn.com/2011/03/25/news/economy/health_care_lobbying/index.htm (citing the Sunlight Foundation's finding that “more than 180 groups have registered to continue shaping the law.”); *Lobbying Tracker, Health Issues*, SUNLIGHT FOUND. REPORTING GRP., <http://reporting.sunlightfoundation.com/lobbying/issue/health-issues> (last visited May 14, 2011); see also Mayer, *supra* note 2; *Health Care Tools*,

tobacco control legislation. When tobacco sellers sensed that they could lose the battle over cigarettes at the state level, they hurried to co-opt decisions of the HHS by hiring as many former insiders as they could and by tailoring a compromise cigarette control statute¹⁵¹ that shielded the largest firms from the toughest controls.¹⁵²

To counter insider maneuvering, counsel representing the public interest should gather data sets, understand search tools for obtaining the fiscal impact information on a rule, assemble the URLs for the legislative history documents, and subscribe to authoritative newsletters.¹⁵³ The opponents of PPACA will come to the conflict prepared; to advocate for your clients you must also be prepared.

X. IMBALANCES OF POWER

Opponents of PPACA, found in think tanks and on op-ed pages, are largely funded by insiders with a financial or ideological stake. Their law firms are very deep in the rulemaking mix, employing the best talent that money can buy. When public sector lawyers assemble their responses, they will need to get fresh data, local impact studies, and wellness or outcome information that your state health department has or can readily obtain.

Be practical as advocates: if implementing this law through this rule is worth the effort, proponents of health care reform must work hard for the survival of this rule, against the opponents' effort to build an insurmountable administrative record explaining why the rule should be weakened or is not justified. Industry counsel will claim a loophole wherever one might be allowed by an interpretation of the statute. If your well-supported rulemaking comment helps HHS to resist an opening for a loophole that the health insurance industry seeks, your work is more likely to be adopted. The satisfaction of public interest lawyers is subtle, for their efforts will have helped countless patients whom they may never meet. If implementation of a key provision of the law fails in the face of the industry-funded attacks on the new rules, a "vacated" rule has no effect, and patients may not be able to get Congress to revisit that particular issue

OPENSECRETS.ORG, *supra* note 2; *Tracking the Paycheck*, OPENSECRETS.ORG, *supra* note 2.

151. Family Smoking Prevention and Tobacco Control and Federal Retirement Program, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781 (2009) (providing the FDA with authority to regulate tobacco products).

152. See James T. O'Reilly, *FDA Regulation of Tobacco: Blessing or Curse for FDA Professionals?*, 64 FOOD & DRUG L.J. 459, 459 (2009) (suggesting FDA professionals would be criticized for "arranging the paperwork for protection of megafirm's market share").

153. See, e.g., *Health Policy Tracking Service on Westlaw*, WEST STORE: TRUSTED LEGAL RESOURCES FROM THOMSON REUTERS (last visited May 14, 2011) <http://west.thomson.com/westlaw/general-counsel/health-policy.aspx>.

for years.

Consider meeting with local officials to discuss the possibility of supporting or coauthoring the comment you plan to file on behalf of your client. Make sure to identify areas of agreement with local governmental entities and officers and underscore common interests or goals in your comments. Ultimately, this debate is about helping the recipients of health care—the constituents of HHS for whom PPACA was adopted—and should not be about raising the share price for health insurance stockholders.

XI. WHO'S GOING TO REVIEW THIS RULE?

The fight is not over when the final rule is published. Judicial review of the rules is very likely to occur. The final rule will be appealed to the circuit courts of appeals, or, for some rules, to the district courts. And there will be strategic efforts by opponents of the reform law who will load the administrative record with arguments which are likely to play well with the judges hearing the case—judges who have life tenure and the power to approve or block an agency's implementing rule, or even the new law itself.¹⁵⁴

Yes, the new law contains ambiguous phrases, which will necessitate court interpretation. In the years since the *Chevron* deference principle was established, deference to agency interpretations has been debated.¹⁵⁵ The attitude of the judge is the wild card in judicial interpretation of regulatory statutes;¹⁵⁶ counsel in health care reform cases must deal with it by making the administrative record as attractive to the reviewing court as possible.

People and organizations with a stake in the law and of its implementing rules need to build the administrative record in support of their client's desired outcome. If a subsection of a proposed rule inadvertently cuts out funds for the State Home for Orphans, for example, lawyers for that state

154. 5 U.S.C. §§ 701–706 (2006).

155. See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984) (establishing a two-part test for determining when a court should give deference to an agency decision and when it should not because deciding power is not within the agency's authority). But see *Melvin v. Astrue*, 602 F. Supp. 2d 694, 703 (E.D.N.C. 2009) (ruling that just because a case involves an administrative agency and an ambiguous statute, it does not mean that the *Chevron* deference principle applies) (citing to *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006)).

156. See Richard J. Pierce, Jr., *What do the Studies of Judicial Review of Agency Action Mean?*, 63 ADMIN. L. REV. 77, 89 (2011) (reporting that a circuit court is approximately 30% more likely to uphold agency action when it is consistent with panel members' ideological preferences, and that ideology is the "most important" variable leading to different judicial determinations regarding agency action).

must be ready to help their clients in the state attorney general's office to make an effective comment.

Whenever Congress has delegated power with ambiguous statutory language, the outcome of interpretation of that power takes place in the courts, and the agency's outcomes are uncertain. How judicial minds will construe the interstices of the health care law is anyone's guess.

XII. POWERS OF PREEMPTION

Federal preemption of state and local powers is a crucial issue for state officials.¹⁵⁷ To win arguments for or against federal preemption of a particular issue, you will need to deal with this highly nuanced constitutional area.¹⁵⁸

If your client is a state or city, learn as much as you can about the reference sources on preemption before the changes appear in proposed rules. Parts of the final rules may prevent your state or city from using its own creativity to solve health care problems. Major health insurers, though regulated by state insurance regulators, dislike state-initiated reforms and will fight them with the Employee Retirement Income Security Act of 1974 (ERISA) or other statutory preemption laws.¹⁵⁹ It is likely that numerous proposed rules announced by federal agencies will demand that each state plan must conform to a federally mandated set of criteria. Be attentive to the preemption doctrine and its practicalities. The use of general agency rulemaking as a predicate to preemption is often challenged in court by those who disagree with the preemption claim.¹⁶⁰

XIII. THE WILD CARDS: WHISTLING AND RELATING

If you represent workers, individual physicians, or nurses, do not overlook the personnel aspects of PPACA. There may be a parade of angry

157. *See generally*, JAMES T. O'REILLY, FEDERAL PREEMPTION OF STATE AND LOCAL LAWS: LEGISLATION, REGULATION AND LITIGATION 2 (2006) (noting that "states view preemption as restricting access to their funds").

158. *Compare* U.S. CONST. art. VI, cl. 2 (establishing the Supremacy Clause and providing for the preemption of state laws by federal laws when the state law is incompatible with the policy of the federal law), *with* *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009) (holding that a state law on drug warning labels is not preempted by federal regulations for drug warning labels issued by the FDA).

159. *See* Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, § 202, 88 Stat. 829, 853-54 (codified in scattered sections of 29 U.S.C.) (setting federal minimum standards for private health insurers).

160. *See generally* Paula A. Sinozich et. al., *Project: The Role of Preemption in Administrative Law*, 45 ADMIN L. REV. 107 (1993) (providing an overview of the preemption doctrine and listing sources for further research).

ex-employees who become qui tam relators, and False Claims Act cases may proliferate. Read § 10104(j)(2) of the new law. Then scan through the Labor Department reference materials the ex-employee can use in making their submissions to the Labor Department under the existing whistleblower adjudication systems.¹⁶¹

The demographic of whistleblowers has changed. Unlike the factory and mine worker complaints of the past, PPACA now empowers a much more sophisticated and highly educated class of persons who will be losing their positions. Some of them will be unhappy, even vindictive. Some of these aggrieved health care workers may contact attorneys for relief. The best advice one can offer them remains, “Get an experienced advocate, don’t go it alone.” The twenty federal whistleblower laws are not all alike.¹⁶² The Administrative Law Judges of the Labor Department will prefer that the individual get experienced counsel. Offer that service and the clients will greatly benefit.

A timely example of the profitability of qui tam relator suits comes in the form of the recent GlaxoSmithKline (GSK) settlement.¹⁶³ Under the settlement, GSK agreed to plead guilty to charges relating to the manufacture and distribution of certain adulterated drugs.¹⁶⁴ The settlement includes a criminal fine and forfeiture totaling \$150 million and a civil settlement under the False Claims Act and related state claims for \$600 million.¹⁶⁵ The DOJ identified the qui tam relator, Cheryl Eckard, who filed her whistleblower lawsuit in the District of Massachusetts.¹⁶⁶ Ms. Eckard will receive approximately \$96 million from the federal share of the FCA settlement amount.¹⁶⁷

XIV. STUDY THE ELIGIBILITY ISSUES

Lawyers who represent lower income families and the poor will have a new set of questions to ponder: the detailed issues of expanded eligibility for health care under the new sets of rules. Anticipation of new patient

161. *The Whistleblower Protection Program*, OCCUPATIONAL SAFETY & HEALTH ADMIN., <http://www.whistleblowers.gov> (last visited May 14, 2011).

162. *See id.* (providing the list and provisions of the twenty different whistleblower statutes).

163. *See* Press Release, Office of Pub. Affairs, Dep’t of Justice, GlaxoSmithKline to Plead Guilty & Pay \$750 Million to Resolve Criminal & Civil Liab. Regarding Mfg. Deficiencies at P.R. Plant (Oct. 26, 2010), <http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html>.

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.*

populations entering the medical service community with payment from Medicaid is good news for public health, because delays in medical attention will make their illnesses or conditions worse.

But the rules determine the reality of patient eligibility, not the rhetoric of the legislative debate that drew so much press attention. (In reality, free health care is not offered by PPACA.¹⁶⁸) Eligibility is complex; lawyers are likely going to have to sort through the new rules to determine whether a denial of subsidized coverage is legal. The general public's expectations from debates on the health care bill—that there would be ample government protections for financial issues and insurability issues—will generate some difficult disputes.

As the health insurance reforms take effect, some early misunderstandings at hospital or surgical billing offices will generate legal questions. The health insurance carriers are constrained and restrained—their is still a for-profit business—and patients of all walks of life will continue to be frustrated by denials and disappointments. Some of these instances will generate requests for legal aid services, some groups of demonstrators will be picketing insurers, and some of these disputes might provoke angry patients or their caregivers to seek guidance. Lawyers are both advocates and peacemakers. Knowing what the PPACA text says can be done now; knowing what the rules will eventually say is dependent on the terms of the final regulations that will be open for public comments.

Consider translating what your clients need to know about health care reform rights into plain English, Spanish, and other foreign languages. Many clients would benefit from plain-language guides to aspects of the health law, understandable by people who are not experts in legal matters. This is a great marketing opportunity for those in elder law, poverty law, or small business counseling. Consider phrasing the material in easy-to-understand questions, such as, “Doesn't the new law require United to pay for this,” or, “Isn't it true that I now have a right to xyz?” Because the local bar association's lawyer referral hotline, or the region's nonprofit legal self-help center if you have one, will get these questions, the practitioner may choose to develop simple marketing tools involving health care simplification documents. These may lead to paying customers with health insurance questions. You are likely to get inquiries wanting you to interpret the statute or predict how the new rules will be implemented. For nonpaying clients, these inquiries would best be answered for the general public by state insurance departments or state attorneys general offices, or by recognized local consumer protection groups.

168. See Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (amending PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010)).

XV. FOLLOW THE MONEY

Prudent lawyers already recognize that these preparatory steps for health care client counseling and commenting will not be inexpensive. You can expect to be offered a proliferation of costly tools and digests. This is a good reason for having a coalition of interested clients who each pay a modest amount for your skilled services. Work with law librarians, who will do what they already do so well—match the hardcover resources with the electronic tools, like Westlaw's health care tracking system that keeps up with statutory and regulatory changes.¹⁶⁹ Look for reliable web news filters and aggregators that have a track record for quality and reliability. Invest prudently in newsletters and ask for sample copies. If you are in a government law office, remember that the Washington offices of the associations of state agency networks like the National Association of Attorneys General and the National Governors Association often disseminate the relevant public information faster than private agencies, and with more accurate predictions.¹⁷⁰

The advantage of subscribing to private health care publications is that their reporters will scoop the agency announcement of the Federal Register publication of a proposed rule, giving you earlier access to the ideas that will be posted in the near future by the agencies. With early warning, you will be able to line up your comments early and to determine what extra set of data will be needed. Again, it is a rulemaking process that demands your clients establish a record in support of their policy choices. And since the agency has already aggregated its supporting data, you will be aggregating your own data either in opposition to or in the same direction, but on a different slant, as the agency.

XVI. USING THE REFERENCE MATERIAL WISELY

To provide the best possible representation for your clients and properly advocate their goals in the rulemaking process, you will need to access a range of materials to ensure that you are fully informed about the proposed

169. See WEST STORE: TRUSTED LEGAL RESOURCES FROM THOMSON REUTERS, *supra* note 153 (providing coverage on delivery, insurance-market and payment reform, state-specific responses, administrative rulemaking, compliance and enforcement issues).

170. See, e.g., *About NAAG*, NAT'L ASS'N OF ATT'Y GENS., http://www.naag.org/about_naag.php (last visited May 14, 2011) (stating that all of the nation's attorneys general are members of NAAG and that its mission is to help attorneys general respond to state and federal issues, individually and cooperatively); *About the National Governors Association*, NAT'L GOVERNORS ASS'N, <http://www.nga.org/portal/site/nga/menuitem.cdd492add7dd9cf9e8ebb856a11010a0/> (last visited May 14, 2011) (stating the National Governors Association's purpose is to provide services to all governors to help them deal with key federal issues as well develop and implement innovative solutions to public policy challenges).

regulations and the varied interests that might be driving the rulemaking process. Therefore, it is essential that you make use of as many resources as possible. Below is a cross section of the many available tools you will need to assist your clients in having a voice in the health care rulemaking process to come.

A. Government Resources

1. The Federal Register

The *Federal Register* is the primary source for the published text of notices, proposed rules, and final rules and regulations, and can be found online.¹⁷¹ The website includes documents from 1995 through the current release. The website provides simple and advanced search functionality or the option to browse through the individual releases.

The Public Inspection Desk is another resource available from the Office of the Federal Register.¹⁷² Regular filing documents that will be published in the following day's *Federal Register* are generally filed at 8:45 a.m. Eastern time.¹⁷³ Special filing documents can be filed at other times and dates prior to publication. And while a day or two might not seem significant, it can provide you with an opportunity to initiate contact with your client and control the schedule rather than waiting for the client to contact you, possibly at the last minute and without enough time to make a well-considered comment.

2. Center for Consumer Information and Insurance Oversight (CCIIO)

The new CCIIO website provides information on its initiatives and programs, regulations and guidance, as well as its collection of insurance information.¹⁷⁴ The CCIIO provides links for news, audio and transcripts of conference calls, fact sheets, and frequently asked questions.¹⁷⁵ Additional information on regulations and guidance is also available.¹⁷⁶

171. It also includes contents and preliminary pages, presidential documents, Sunshine Act meetings prior to March 1, 1996, reader aids, and corrections. *Federal Register Contents*, GPO ACCESS, http://www.access.gpo.gov/su_docs/aces/fr-cont.html (last visited May 14, 2011). The *Federal Register* can be found online at <http://www.gpoaccess.gov/fr/> or at <http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>.

172. *Electronic Public Inspection Desk*, OFFICE OF THE FED. REGISTER, <http://www.ofr.gov/inspection.aspx> (last visited May 14, 2011).

173. *See id.*

174. *Center for Consumer Information and Insurance Oversight*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://cciio.cms.gov> (last visited May 14, 2011).

175. *Id.*

176. *Regulations and Guidance*, U.S. DEP'T OF HEALTH & HUMAN SERVS.,

The regulations and guidance page also provides separate information and resources for responding to requests for comment.¹⁷⁷

3. *Regulations.gov*

As mentioned before, Regulations.gov allows interested parties to search for rulemaking notices as well as proposed and final rules, file their comments electronically, and even comment on other comments.¹⁷⁸ The website provides information from nearly 300 federal agencies. Much like electronic case filing in federal court, do not wait until the last minute before a comment deadline to experiment with the website for the first time. It is important to be familiar with the process for submitting comments. Instructions for filing comments electronically are available on the website.¹⁷⁹

B. *Private Resources*

1. *National Association of Insurance Commissioners (NAIC)*

The NAIC has added a special section on its website for PPACA and state insurance regulation.¹⁸⁰ The site is maintained in association with the NAIC's Center for Insurance Policy and Research, which the NAIC established in 2009 to provide information and analysis for government officials, agencies, and policymakers.¹⁸¹ Because Congress directed HHS to consult with the NAIC in developing certain implementing regulations under PPACA, the NAIC is an important resource for tracking the progress

<http://cciio.cms.gov/resources/regulations/index.html> (last visited May 14, 2011).

177. *Requests for Comment*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://cciio.cms.gov/resources/comments/index.html> (last visited May 14, 2011).

178. *About Us*, REGULATIONS.GOV, <http://www.regulations.gov/#!aboutUs> (last visited May 14, 2011).

179. *Help*, REGULATIONS.GOV, <http://www.regulations.gov/#!help> (last visited May 14, 2011).

180. *Patient Protection and Affordable Care Act & State Insurance Regulation*, NAT'L ASSOC. OF INS. COMM'RS & CTR. FOR INS. POLICY & RESEARCH, http://www.naic.org/index_health_reform_section.htm (last updated Dec. 17, 2010).

181. *About the CIPR*, NAT'L ASSOC. OF INS. COMM'RS & CTR. FOR INS. POLICY & RESEARCH, http://www.naic.org/cipr_about.htm (last visited May 14, 2011).

of its recommendations to HHS.¹⁸² The NAIC website also includes information for consumers, employers, and seniors.

2. *Trade Associations*

Although we have cautioned against relying on trade associations to speak for your clients, many will provide you with insights into how your clients and their industry peers are approaching PPACA regulations. Of course, it is important to be aware that no association's interests will align perfectly with those of each of their constituents. You will have to maintain a degree of skepticism to ensure that you are speaking for your client and not just adopting the homogenized position of the association.

C. *Commercial Resources*

Multiple vendors offer information and analysis for a price that often exceeds the viability of legal aid or public interest law group subscriptions. A skilled law librarian is your best intermediary for these selections.

CONCLUSION

Some see opportunities where others see problems. Small firm lawyers outside the political mainstream of big-city megafirms may be feeling overwhelmed by the prospect of commenting on complex federal rules implementing a huge new statute. This is true, but the converse is also true: adversaries who are working against your client's long-term health care interests are hoping your client will remain silent as they comment, meet, petition, and litigate over the new health care rules. They know the rulemaking process under PPACA is a formidable challenge for you. It is a tsunami they can foresee, while smaller and solo lawyers like you, who have clients needing health care assistance, are just standing on the shore looking out into the vast regulatory ocean. If this article encouraged you to participate, please follow our advice and plunge in.

182. See PPACA, Pub. L. No. 111-148 § 2715(a), 124 Stat. 119, 132 (2010) (requiring HHS to consult with the NAIC to “develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, in compiling and providing to enrollees a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage”); § 1323(b)(8)(A), 124 Stat. at 195 (requiring the HHS to collaborate with NAIC in promulgating regulations to establish additional requirements for a community health insurance option); *id.* § 1341(b)(1), 124 Stat. at 209 (requiring the HHS to consult with the NAIC in developing regulations for the transactional reinsurance program for individual and small group markets in each state); § 3210(a)(1), 124 Stat. at 461–62 (requiring the HHS to request that the NAIC review and revise the standards for benefit packages for certain Medigap plans).