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# Patient Protection and Affordable Care Act of 2010: Summary, Analysis, and Opportunities for Advocacy for the Academic Emergency Physician

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## Abstract

The Patient Protection and Affordable Care Bill, commonly referred to as the "Health Care Bill" or the "Health Care Reform Bill," became enacted in March, 2010. This article is a review and analysis of the sections of this Act that are relevant to researchers and teachers of emergency care. The purpose of this document is to serve as a citable reference for interested parties and a reference to quickly locate the sections of the Bill relevant to academic emergency physicians. When appropriate, text was copied verbatim from the bill. The source of the downloaded Act, and the page numbers of the text sections, are provided to help the reader to find the sections described. This review is presented in two parts. Part 1 presents 11 sections extirpated from the Act, with short interpretations of the significance of each section. Part II presents an analysis of the sections that the authors believe represent opportunities for emergency care researchers and teachers to make the most impact, through active involvement with the various departments and agencies of the federal government that will be charged with interpreting and implementing this Act. The Act contains sections that could lead to new funding opportunities for research in emergency care, especially for comparative clinical trials and clinical studies that focus on integration and efficiency of health care delivery. The Act will establish several new institutes, centers, and committees that will create policies highly relevant to emergency care. The authors conclude that this Act can be expected to have a profound influence on research and training in emergency care.

## INTRODUCTION

This represents a two-part analysis of the recently enacted "Patient Protection and Affordable Care Act," with a focus on sections that are of high impact to the mission of the Society for Academic Emergency Medicine (SAEM). The first section was written by one author (JAK) and consists of an extirpation of relevant sections of the text of the Act, followed by short interpretations of the probable impact or importance of each section from the perspective of academic emergency medicine (EM). The second part is the commentary provided by an academic EM faculty member with interest in advocacy (JDW). The purpose of this report is to identify opportunities for academic emergency physicians to take actions to enable the translation of this Act into improved emergency care.

The formal short title of the Act being examined is the "Patient Protection and Affordable Care Act" ("the Act"), and is codified as HR3590. The source of the text for this analysis

was downloaded from the United States Senate URL http://thomas.loc.gov/cgi-bin/thomas at 06:00 EDT on Friday, March 26, 2010. This web page demonstrates that seven versions of the bill existed; the Act passed in both houses of Congress represents Item #7 on the URL accessed on the above referenced time/date, and is a 906 page document.

For part I, one author (JAK) examined the ten-page table of contents of the Act for all topics relevant to the mission statement of SAEM, and then read each of those sections of the Bill that contained relevant content. Next, the examiner performed a separate free text (CTRL-F) search of the entire document for each of these words: emergency, regionalized, comparative effectiveness, randomized clinical trial, training, dollars, and research. The examiner then read the surrounding text to determine potential relevance. The examiner read approximately one-third of the entire Act.

The examiner then ranked the extirpated sections in order of importance relevant to the SAEM mission. To reduce ambiguity, the sections are referenced to the page number of the Act in this manuscript.

In part II, a second examiner (JDW) read the part I analysis and the relevant portions of the Act, and then provided a contextual analysis of selected sections. Potential actions that could be taken by the SAEM Board of Directors, committees, task forces, or individual members to maximize the positive impact of the Act upon emergency care are suggested.

No portion of this analysis is intended to substitute for or replace any part of the official strategic plan for SAEM, approved by the Board of Directors on March 5, 2010.

#### **PARTI**

## 1. Section 1302, page 45

#### Emergency care is a new entitlement for all American citizens

This preamble sets the scope and significance of the Act. The bottom of page 45 establishes a new federally funded entitlement program, which grants all US citizens access to emergency services.

<u>Interpretation</u>: At minimum, this codifies access to emergency services as a new entitlement granted to US citizens without a direct financial cost to the patient. A more extreme interpretation would be that access to emergency care is a right of citizenship. Indeed, emergency services are listed in the Act before any mention of hospitalization. This is fundamental to setting research priority, and establishing the need for training emergency care providers.

#### 2. Section 498D, page 403

**Support for emergency medicine research**—This section specifically describes the requirement for the Secretary of the Department of Health and Human Services (HHS) to support federal programs administered by the National Institutes of Health (NIH) and Agency for Healthcare Research in Quality (AHRQ) to

"Expand and accelerate research in emergency care systems and emergency medicine, including:

- 1. The basic science of emergency medicine;
- **2.** The model of service, delivery and the components of such models that contribute to enhance patient outcomes;
- 3. The translation of basic scientific research and to improve practice; and

**4.** The development of timely and efficient delivery of health services."

<u>Interpretation:</u> This is a major milestone for emergency medicine, only specialty to which any section of the Act is exclusively dedicated. For example, there is no other section dedicated specifically to research in any other medical specialty, such as surgery, internal medicine, pediatrics, or anesthesiology.

# 3. Section 498D, page 403. Part B

**Pediatric emergency medical research**—The Act specifies that, as in the preceding section, HHS coordinate with NIH, AHRQ, the Centers for Disease Control and Prevention (CDC), and other agencies to expand research in pediatric emergency medical services, specifically to:

- **a.** Examine the gaps and opportunities in pediatric emergency care research, and strategies for optimal organization of funding of such research,
- **b.** Expand the role of pediatric emergency services and integrate them as a critical component of overall health,
- **c.** Enhance system-wide pediatric emergency care planning.
- d. Expand pediatric training in professional education
- **e.** Fund research in pediatric emergency care specific on efficacy, safety, health outcomes, and medications used in infants, children, adolescents, and emergency care settings in order to improve patient safety

The text subsequently describes the definition of impact research, and the manner by which appropriations will be authorized.

Interpretation: This section extends the emergency medicine research provision noted above, and specifically outlines the need for more research in pediatric emergency care.

#### 4. Section 3505. Page 404

**Trauma Care Centers and Service Availability**—This section and the section that follows describe the qualifications of trauma centers, and the method for paying for uncompensated care costs. Under Part H, the Act describes a requirement for states to grant and promote universal access to trauma care. On page 409 of the Act, the dollar amounts to enable this are specified, beginning with \$100 million dollars for fiscal year 2009, and "such sums as may be necessary for each of fiscal years 2010 through 2015".

Importance: This section highlights the federal commitment to maintaining a strong system of integrated, regionalized trauma care in the United States. This is especially important in an era when the number of trauma care providers appears to be decreasing. This commitment to the funding of regional trauma networks should be reassuring to those who have an interest in caring for patients with this time-critical problem, potentially allaying suspicions that the federal government might not fund such efforts adequately. Recruitment of young physicians to careers in disciplines providing trauma care may be enhanced.

# 5. Section 6301 page 609

**Patient Centered Outcomes in Research**—This section spans approximately 15 pages, in which a need for research in *comparative clinical effectiveness* is described. On page 610, the law specifies the need to require a new Patient-Centered Outcomes Research Institutes (PCORI) that will be funded by the Patient Centered Outcomes Research Trust Fund (PCORTF). The purpose of this institute is "to assist patients, clinicians, purchasers,

policymakers in making informed health decisions by advancing the quality and relevance of the evidence concerning the manner in which diseases, disorders, and other health conditions can effectively, and appropriately be prevented, diagnosed, treated, monitored and managed through research in evidence sent through the system...." Its duties, described on page 610–611, include establishing research priorities, establishing research agendas, and issuing contracts for funding and conduct of research. On page 613, the law now requires that this institute "appoint permanent, or ad hoc, expert advisory panels as determined appropriate to assist in identifying research priorities".

The PCORI must convene certain expert panels relevant to the oversight and management of comparative effectiveness research. One particular expert panel to be administered by the PCORI, described on page 613, is an expert panel for *randomized clinical trials*. Additionally, page 614 describes a *Methodology Committee* which will have 15 members appointed by the Comptroller General of the United States and will include health care professionals, biostatisticians, and research methodologists. The primary function of the Methodology Committee is primarily to set methodological standards for research in comparative effectiveness research.

Page 615 describes a process for evaluating peer-reviewed research. This is a somewhat difficult section to read, but it appears to specify a method by which peer-reviewed research is to be evaluated by agencies of the federal government for establishing funding priority. Although not specified, this would imply that the Methodology Committee, or perhaps another ad hoc committee, will be created to oversee the peer-review process. Interestingly, on page 615, it is specified that the PCORI "may utilize the peer-review process of appropriate medical journals".

Page 621 describes the training of researchers stating,

"The AHRQ in consultation with NIH shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for training of researchers and methods used to conduct research, including systematic reviews that existing research, and primary research, such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards..."

Underneath this section, which continues on page 622, the law prescribes that the

"Secretary of Health and Human Services shall coordinate with federal health programs to build data capacity for comparative effectiveness research, including development and use of clinical registries and health outcomes data networks."

Interpretation: These pages describe the need for increased comparative effectiveness trials to be conducted in human subjects. No part of this text prescribes any need for increased funding of basic sciences, stem cell research, or any other pre-clinical area. No mention is made of genomics, molecular medicine, or any other technology development. This is a section that is particularly relevant to research that members of our Society are well-qualified to direct and conduct in emergency care populations. There are several opportunities for service, including the Clinical Trials and Methodology Committees. The section on page 621 essentially specifies many of the criteria that are being used the SAEM Research Fellowship Credentialing Committee.

The funding for these efforts is described on page 623. Again, the PCORI is funded by the PCORTF. For fiscal year 2013, an amount equal to \$1 per beneficiary will be committed for funding these initiatives. This funding commitment increases to \$2 per beneficiary starting

in 2014. The fund will be created in 2010 with a \$10 million deposit, with annual funding increasing to \$150 million by 2012.

# 6. Section 350, on page 400

This section describes the **design and implementation of regionalized systems for emergency care**. This is an additional section that adds to the trauma systems section already described. On page 400, the law prescribes the need for not fewer than four multi-year contracts or competitive grants to eligible entities to support pilot projects to design, implement, and evaluate innovative models in regionalized comprehensive and accountable emergency care and trauma systems.

Interpretation: This shows the federal government's recognition of previous expert panel recommendations to increase funding for regionalization and networks of emergency care. The one interesting and potentially disappointing observation is the lack of any mention or reference to the Emergency Care Coordination Center (ECCC) in this or another other part of this act.

#### 7. Section 271, page 519

Under part D on page 519, the law prescribes the creation of a **United States Public Health Sciences Track**, with the authority to grant appropriate advanced degrees in public health epidemiology and emergency preparedness and response. The language of the Act then states the number of medical students, dental students, and nursing, public health, and allied health students who should be trained, as well as preferred locations. The implementation of the track will be overseen by the Surgeon General.

Interpretation: This section of the Act suggests the likelihood of increased funding to medical schools that have well-established schools of public health.

## 8. Section 3021, page 271

This section begins on page 271 and specifies the creation of the **Center for Medicare and Medicaid Innovation**. This new center will be created within the Centers for Medicare and Medicaid Services. Its purpose will be to select models of care as described on page 272. These include the mechanism(s) by which doctors will be paid, and requirements to qualify for special funding for patients with cognitive impairments with older age (inability to perform two or more activities of daily living or cognitive impairment). Most importantly under this part is a section at the bottom of page 272 that prescribes:

"Varying payment to physicians who order advanced diagnostic imaging services as defined in Section 1834, E1B [note: this is the Social Security Act and advanced diagnostic imaging service refers to CT, MRI and nuclear medicine] according to the physician's adherence to appropriateness criteria of such services as determined in consultation with physician specialty groups and other relevant stakeholders."

Interpretation: The latter provision has profound implications to test ordering in emergency medicine, inasmuch as 6% of all ED patients receive some type of CT scan. This raises the opportunity for research aimed at decreasing CT and MRI utilization within the emergency department, using decision rules and computer-based methods as gating instruments. It is a concern that the Act is silent regarding the extension of medicolegal protections to clinicians who practice evidence-based, cost-saving innovations in their care of individual patients.

# 9. Section 2707, page 208

The Medicaid Emergency Psychiatric Demonstration Project dedicates \$75 million toward a demonstration project to test methods to improve psychiatric care.

Interpretation: This represents one relevant example of how the Act addresses the immediate, dire need for improved access to and delivery of psychiatric care. This is a recurring theme throughout the Act.

#### 10. Section 5503, page 538

This section describes a 75% increase in funding for training in primary care and in general surgery.

Importance: This leaves relatively little room for increases in non-primary care or non-surgical specialties.

# 11. Section 5505, page 542

Rules for counting resident time for didactic and scholarly activities, and other activities—Page 542 of the Act codifies that didactic teaching and seminars will be counted toward resident equivalency (meaning payment for the residents' time in these activities will be reimbursed by the government). However, there is a specific section on page 543 that specifies a different interpretation of time spent doing research, stating, "... research activities that are not associated with treatment or diagnosis of a particular patient, shall not be counted toward the termination of the full-time equivalency."

Importance: The government will not fund the time spent by residents performing research as a recognized expense of residency training, even if such research is deemed a requirement of residency training.

# **PART II**

#### **SAEM in Action**

Patient Protection and Affordable Care Act—Many special interests commit immense resources to influence the form and content of every document that winds its way through the complex maze of legislative processes in the US Congress. Their efforts may result in a single phrase (or lack of a single phrase), but these few words (or lack thereof) can have profound influences. The preceding extirpation of the "Patient Protection and Affordable Care Act" provides many phrases that clearly indicate an escalation of the formal degree of recognition of the pivotal role of emergency care toward the overall health and safety of the American public.

This brief review will focus on a few tangible action steps for academic emergency medicine and the members of SAEM to undertake in response to the Health Care Act. Specifically, the academic emergency medicine community can focus on engagement with the legislative process in guiding interpretation of several important sections of this legislation. Enormous opportunities now exist for emergency care teachers and researchers to influence the way that this Act is transformed to policies that affect the day-to-day practice of emergency medicine, and the training of emergency care specialists.

#### Item 2. Section 498D, page 403

**Support for emergency medicine research**—This section sends a direct and unmistakable message to the NIH, AHRQ, and CDC (which reside under the umbrella of the Department of Health and Human Services) regarding the importance of advancing

emergency medicine research in several different key arenas. The dedicated efforts of many individuals on collaborative ACEP/SAEM/AAMC efforts appear to have paid off in the language of this section. It suggests a sentinel moment that codifies the need for emergency care to "catch up" to other specialties in terms of federally funded, patient-oriented research. SAEM members have the opportunity to further guide this provision by continuing to provide face-to-face input to members of the NIH and AHRQ regarding specific, testable hypotheses that have the highest priority and are responsive to the call for increased basic science knowledge, its translation into clinical protocols, and their efficient and economical delivery. These testable hypotheses should be composed into a written consensus document that is endorsed by SAEM, and potentially other professional organizations relevant to emergency medicine. Of key relevance to this effort, Drs. Roger Lewis and Amy Kaji have written a manuscript (currently under review) that summarizes the NIH Roundtable. That manuscript provides many structural elements needed for the drafting of a consensus document that is responsive to the opportunities described by this section.

This consensus document could be initially constructed by a collaborative effort of the SAEM NIH Task Force, together with input from several other SAEM committees, including the Research and Graduate Medical Education Committees and the Board of Directors, and potentially including input from other emergency medicine organizations. Such a consensus document would be most effective if submitted by the president of SAEM with official endorsement from the Board of Directors for consideration to the Secretary of Health and Human Services, Kathleen Sibelius, who guides some of the largest sections of growth in the US government. There are several key players within her administration with whom communication could occur: Dr. Howard Koh, the Assistant Secretary for Health and Dr. Anand Parekh, the Deputy Assistant Secretary for Health. Both have participated in emergency preparedness program development and bring a physician's perspective to research infrastructure.

An important dialogue suggesting changes in emergency medicine research priorities and infrastructure among leaders and collaborators in our field can be read on pages 37–48 of The National Emergency Care Enterprise: Advancing Care Through Collaboration: Workshop Summary (2009).

http://www.nap.edu/openbook.php?record\_id=12713&page=37

In addition, the structure of the Department of Health and Human Services is a fascinating story all by itself. For an organizational overview, visit: http://www.hhs.gov/afr/management/mission/index.html. The grant opportunities available within this web maze are staggering.

# Item 5. Section 6301 page 609

Patient Centered Outcomes in Research—This is low-hanging fruit for those in emergency medicine-based translational sciences. The Patient-Centered Outcomes Research Institutes will be brand new, and will require experts in emergency care methodology. Those leaders can then help guide funding to emergency medicine scientists whose primary areas of focus are outside of basic science.

The Emergency Care Coordination Center (ECCC), though not mentioned in the Health Care Act, is well positioned to coordinate, analyze, and assist in the dissemination of this type of research in the future.

# Item 8. Section 3021, page 271

Center for Medicare and Medicaid Innovation (CMI)—The idea of a "Center of Innovation" appears to be borrowed from the business community, and represents a relatively novel concept for a Bill involving medicine and health care delivery. Rather than a focus on immediate change (such as is exemplified by a blood transfusion), centers for innovation support change through trials and pilots with a long-term view (analogous to medication to stimulate red blood cell production). Most well-known current Centers of Innovation are in the private sector, and focus on collaboration between private and public forums, enhancing productivity while cutting costs and embracing technology to overcome fragmented communication. The idea of an emergency care academician belonging to a center of innovation with a specific, finite task is an exciting one. An example task is the development of an emergency department-based decision rule for the use of abdominal imaging in pediatric trauma. Such an effort is already in development by the Pediatric Emergency Care and Research Network. A vision exists not only for the development of emergency care-driven evidence, but also follow-up government aid for evidence dissemination for widespread implementation.

Robert Mechanic, MBA, and Stuart Altman, PhD, muse in their March 2010 NEJM editorial "Medicare's Opportunity to Encourage Innovation in Health Care Delivery" that "Several aspects of the proposed CMI offer hope that this effort could be fundamentally different from previous Medicare-sponsored experiments."1 First, direct oversight of pilot programs and opportunities for immediate expansion will lie in the hands of the HHS Secretary. Prior CMS demonstration projects have required Congressional approval, resulting in long delays and the attenuation of potentially important programs. This CMI structure could accelerate projects with demonstrated early results for regional testing. Though this seems innately opposed to the checks and balances of government process, we trace even our success in agriculture to this model of small- to large-scale rapid innovation and change. Dr. Atul Gawande gives further insight into this process in his recent December 2009 New Yorker article. 2 Second, this new center would not require pilot programs to be initially budget neutral, allowing for long-term growth and startup investment costs. Mechanic and Altman propose that a successful CMI will require leaders who "think outside the box", aren't afraid of occasional failure, and regularly interact "with innovators and build on existing knowledge about what works."1

Thinking in an innovative way within a government bureaucracy begs participation from "outsider" emergency care thought leaders who have historically shied away from the arduous task of patiently solving long-term problems in a less-than-perfect government system. Physicians in general have a clarion call to be, now more than ever, "at the table or on the table."3

Emergency care academicians, with this new legislation, have a clear rallying point for active participation and shaping of the health care system. At this writing, the current administration is likely to appoint Dr. Donald Berwick, a pediatrician and head of the Institute of Healthcare Improvement, to head CMS. His team would include Dr. David Blumenthal, the national coordinator for health information technology. These two innovators represent prime contacts for emergency care involvement at an early phase in CMI definitions of tasks and missions. Center for Innovation subsections to feature emergency care models for evidence-based practice and decision rules to streamline costs, for example, are plausible in the near future.

Health care reform has delivered a new opportunity for academicians in emergency medicine, via a call for innovation, creativity, and focus on rapid translation of basic science to patient care delivery and outcomes. Emergency medicine is a specialty born of innovation

and creativity. Now out of its infancy, it is positioned to leap forward via meaningful participation in federally funded comparative clinical effectiveness research, engagement in responsible health care delivery, and the education of the next generation of emergency care providers and leaders.

**Summary**—The Patient Protection and Affordable Care Act of 2010 contains at least 11 sections that have direct relevance to academic emergency medicine. The Act explicitly names emergency care as a right to US Citizens. One section specifically calls for increased research in emergency medicine. The Act calls for a new Institute that will promulgate patient-oriented research including clinical trials, and will create a new Methodology Committee. The Act will also create a new Center for Medicare Innovation that will be charged with controlling the use of advanced imaging services.

# CONCLUSIONS

This Act has prioritized and increased funding for patient-oriented emergency care research; several immediate opportunities exist for academic emergency medicine to influence how this Act will be interpreted, and the Act has created several new opportunities for academic emergency medicine experts to serve on important advisory panels and committees.

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