

## **The Illinois Hospital Community's Response to Disease-Specific Regulation**

### **White Paper of the IHA Task Force on Disease-Specific Regulation**

January 5, 2010

#### ***Background***

Governor Pat Quinn, on August 18, 2009, signed into law Public Act 96-514, then the state's newest disease-specific statute. This law, designed to allow the creation of stroke systems of care in Illinois, identifies hospitals capable of providing emergent stroke care and directs EMS providers to transport possible acute stroke patients to these hospitals.

While the State has an abundance of existing disease-specific regulations, Public Act 96-514 is unique: not only has it altered EMS patient transport patterns for a specific patient population (i.e. stroke patients), it also explicitly allows EMS to bypass hospitals not able to provide emergent stroke care, a first for any disease-specific regulation in Illinois.

While Public Act 96-514 was a proposal of the American Stroke Association, a division of the American Heart Association, IHA collaborated with the national association on the state legislation from 2007-2009. When it became clear that the provisions in the stroke bill required significant member input, the IHA Policy Council in 2008 appointed a diverse 26-member Stroke Task Force and charged the group with developing IHA policy on the issues in the stroke legislation. Once the IHA Board of Trustees approved the Stroke Task Force, IHA successfully advocated for legislation that incorporated those recommendations.

Public Act 96-514 was part of the American Heart Association's goal to pass similar disease-specific legislation in as many states as possible. Following passage of Illinois' legislation, the national organization expressed a desire to pursue additional disease-specific regulatory changes for patients suffering an ST-Elevated Myocardial Infarction (STEMI). While the organization has committed to not pursuing state regulatory changes in 2010, it has approached IHA about implementing a similar system for STEMI patients as is being employed for stroke patients.

At its January 2009 meeting, the IHA Board of Trustees discussed challenges posed by legislation attempting to prescribe the management of specific diseases or conditions. After discussing and approving stroke systems of care recommendations, the Board passed a formal resolution directing staff to create a white paper addressing legislation prescribing treatment protocols based on specific diseases. The Policy Council appointed the Task Force on Disease-Specific Regulation in response, and charged the membership group with developing a white paper on the assessment and impact of disease-specific legislation.

The Task Force on Disease-Specific Regulation met three times and created a set of guiding principles with which to assess disease-specific regulation proposed in the future. The principles as outlined below are intended to guide IHA's assessment of, and response to, disease-specific legislation and regulation, acknowledging that not all disease-specific regulation is alike and that the weight given to each principle will depend on the facts surrounding the specific proposal.

## **GUIDING PRINCIPLES**

### **Recommendations of the IHA Task Force on Disease-Specific Regulation**

#### **OVERALL PHILOSOPHICAL RECOMMENDATIONS:**

- Illinois hospitals are committed to providing all patients exceptional timely, equitable, high-quality patient-centered care.
- Disease-specific regulation should improve patient outcomes and not adversely affect hospitals' or clinicians' ability to provide patient care within their capabilities and resources. To the extent possible, the regulation should stimulate broad-based access to the desired service.
- IHA does not support the legislation or regulation of clinical protocols. Doing so freezes treatment protocols in time, therefore putting in jeopardy clinicians' ability to provide services based on the most current, nationally-recognized, evidence-based practices, and possibly disincentivizes scientific advancements. Because science, and therefore medicine, advances rapidly, IHA cannot support government legislation or regulation that incorporates clinical protocols, as legislative and regulatory processes are not designed to change easily.
- IHA encourages efforts to support and strengthen the EMS system with funding, training, and infrastructure, and recognizes it as a critical partner in the provision of timely, safe, and effective disease-specific emergent care.

#### **DISEASE-SPECIFIC REGULATION ASSESSMENT**

When disease-specific regulation that affects Illinois hospitals is proposed, IHA will evaluate the proposed regulation by performing assessments of each of the following:

- The public health need,
- The proposed regulation,
- The hospital/health care delivery system response to the public health need,
- The regulatory environment, and
- The financial impact of the proposal.

#### **Public Health Assessment**

- Does data demonstrate a clear public health need throughout Illinois?
- If there is a public health need, how is it being met in Illinois, and in other states?
- What is the ideal way to solve the public health need?
- Is government action (i.e. regulation) necessary to meet said public health need?

#### **Proposed Regulation Assessment**

- Does the proposed regulation appropriately address the public health need, or should it be revised?

- Is there clear, compelling evidence demonstrating the efficacy of the proposal in addressing the public health need?
- What consequences could result from enacting the regulation?
- What alternatives to regulation (i.e. public-private partnerships, voluntary compliance with nationally-recognized, evidence-based standards, etc.) have been effective in areas with similar public health needs?
- What existing regulation, if any, addresses the public health need?

#### Hospital/Health Care Delivery System Role & Impact Assessment

- How are Illinois hospitals addressing the public health need, as compared to hospitals nationwide?
- How do Illinois hospitals' outcomes compare to those nationwide when using nationally-recognized benchmarks that address the public health need?
- How would the proposal affect Illinois' health care delivery system?
- How would patients be affected by the regulation?

#### Current Illinois Environment Assessment

- Does the public – and other stakeholders – believe the proposed regulation would effectively address the public health concern?
- Is there public pressure to address this public health need?
- How likely is the regulation to be enacted?

#### Financial Impact Assessment

- What short-term and long-term costs are associated with implementing the proposal and with not implementing the proposal?
- How would the regulation affect patients financially considering Medicare, Medicaid and other third party payer reimbursement policies?
- What funding sources are available for hospitals, other stakeholders, and the State, to implement the regulation?

#### **DISEASE-SPECIFIC REGULATION: GUIDING PRINCIPLES**

If IHA determines, based on the above assessments of the proposed policy, that disease-specific regulation is appropriate, the Task Force on Disease-Specific Regulation recommends IHA, and the Illinois hospital community, pursue regulation that considers the following criteria:

#### Quality

- The disease-specific proposal must improve patient access to care or it must improve the quality of patient care provided, or both.

- Regulation should avoid defining specific treatment protocols for hospital-based clinicians.
- Disease-specific regulation should be consistent with existing standards of professional and/or regulatory bodies.
- If hospitals are required to collect and/or submit data or outcome measurements, data protection measures must be included:
  - Patient-level quality data should be considered privileged and strictly confidential.
  - The proposed data collection entity should be appropriate to the proposal, and should preferably be a neutral third party.
  - Timely hospital-specific data may be disclosed by the State after a reasonable period of time following implementation (e.g. 2-3 years). Hospitals should be provided the opportunity to validate the accuracy and reliability of the data before it is disclosed.
  - Quality data collected by the State should, where possible, be limited to data already collected by affected hospitals.
- Data collected by the State should be purposeful, made available to hospitals for quality improvement, and should not be used to penalize hospitals (fines, loss of licensure/designation, etc).
- If the proposal allows for hospital designation by the state based on certification achieved through private, nationally-recognized certification bodies:
  - Certification should be based on evidence-based standards and be considered a distinct process from state designation.
  - Designation, if necessary, may be performed by the state provided that hospitals are provided due process, and are allowed to opt-in and out of designation.
  - Under this model, certification cannot be suspended or revoked by the State, but designation may be suspended or revoked in extreme circumstances to prevent harm to patients.
- Mechanisms to limit the amount of time the disease-specific regulation is in place or to assume its periodic review (i.e. sun setting the policy, making it subject to appropriation, dependent on demonstration of positive outcomes) are considered appropriate tools for inclusion.
- Pilot programs and similar initiatives to incrementally implement disease-specific regulation may additionally be considered appropriate tools to include.

#### Access

- The proposal must afford regional flexibility and utilize existing resources.
- If the proposed regulation creates a system of care, whereby hospitals are identified as facilities capable of providing disease-specific care, an adequate number of hospitals must be capable of providing disease-specific care to minimize the risk of negative

consequences, patient harm, and to help ensure implementation of a realistic and feasible regulation. Systems of care involving hospitals must be inclusive and not prevent patients from receiving timely, exceptional, high-quality care.

- The State should provide hospitals affected by the regulation the opportunity to work with other affected stakeholders to advise the State on the development and implementation of the regulation.
- If the regulation affects EMS patient transport, patients should be transported to the first available, most appropriate hospital as determined by each EMS Region.

#### Cost

- The State should incentivize, not penalize, hospitals to comply with disease-specific regulation.

#### ***Conclusion***

The IHA Task Force on Disease-Specific Regulation recommends all proposals to regulate patient care based on a disease or condition – particularly any proposal that affects hospitals’ ability to provide patient care – be carefully assessed and evaluated according to the framework provided in these guiding principles. Some disease-specific regulation may assist health care providers in improving patient care and should not be summarily discounted: disease-specific regulation should assist, not hinder, the ability of the Illinois hospital community to provide the highest level of patient care.

Illinois hospitals, diverse in scope and size, are truly committed to providing all patients exceptional, timely, equitable, high-quality patient-centered care. As demonstrated by Public Act 96-514, which identifies hospitals capable of providing stroke care and allows EMS providers to transport stroke patients to these identified hospitals, disease-specific regulation often impacts Illinois hospitals and the very patients they serve. Hospitals play an integral role in the provision of essential health care services throughout Illinois, and as such, must be supported in their efforts to improve patient care.