Regulatory Change: A Pathway to Eliminating Seclusion and Restraint or "Regulatory Scotoma"?

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Historical and current experience indicates that regulatory changes in seclusion and restraint practice are often spurred by patient abuse but can ultimately enhance protection for consumers, prevent use of seclusion and restraint, and help transform care so it becomes recovery oriented. Reports of deaths related to restraint and seclusion fueled recent national regulatory changes and a federal agenda to eliminate their use. Some states, many facilities, and the federal initiative have focused on seclusion and restraint prevention and alternatives and have made important strides in reducing and eliminating these practices. However, new national regulations lessen previous oversight requirements, heighten risk, and threaten gains in reducing and eliminating such practices. Courageous, knowledgeable leadership is needed to challenge these minimum-practice thresholds and prevent seclusion and restraint "regulatory scotoma." (*Psychiatric Services* 59:194–196, 2008)

Regulations governing seclusion and restraint have the force of law and can elevate standards of practice. These standards are often crafted reactively after people are hurt in order to prevent further harm and usher in treatment reform. The Lunatic Asylums Act of 1842, for example, was enacted after publicized restraint abuses, and together with the Non-Restraint Movement it was credited with abolishing use of mechanical restraint in the United Kingdom (1,2). When the Non-Restraint Movement began in the United States, several facilities, such as Danvers State Hospital and Northampton State Hospital in Massachusetts, eliminated restraint use (2). In order to further this effort and address abuses at other facilities, Boston psychiatrist L. Vernon Briggs lobbied the legislature to enact the state's first statute to restrict the use of seclusion and restraint and ensure continual physician oversight. Despite fierce opposition, the legislation prevailed and reduction in seclusion and restraint resulted (2).

Current perspective

More recently, seclusion and restraint standards for psychiatric settings were in the media spotlight as a result of the *Hartford Courant's* 1998 Pulitzer-prize winning exposé on seclusion and restraint deaths. These articles initiated a U.S. General Accounting Office investigation and Congressional hearings, which ultimately confirmed the *Courant's* findings—that is, that restrained and secluded consumers were traumatized and harmed and that many died as a result of these often violent procedures. The Health Care Financing Administration, now called the Centers for Medicare and Medicaid Services (CMS), rapidly issued an Interim Final Rule in 1999 on hospital conditions for participation governing patients' rights (3). The Interim Final Rule was noteworthy for the speed at which it was created and implemented, for eclipsing the Joint Commission standards, and for imposing new requirements, most notably the "one-hour rule," which states that physicians or licensed independent practitioners are required to perform a face-to-face evaluation of the person in seclusion or restraint within the first hour of initiation.

Other statutory and standards changes followed. In 2000 the Children's Health Act established national standards restricting the use of seclusion and restraint in all public and private health care facilities that receive federal financial assistance, including hospitals, nursing facilities, psychiatric facilities, and intermediate care facilities. The following year, the Joint Commission issued new behavioral health care standards, some of which exceeded the Interim Final Rule's standards, such as requiring a face-to-face reevaluation by a physician or a licensed independent practitioner, debriefing episodes with staff and consumers, and more documentation and data collection to monitor use. The combination of regulatory advances kept health care organizations focused on elevating the oversight and practice of seclusion and restraint.

Federal and state efforts

Implementation of the Interim Final Rule was subsequently bolstered in 2003 by the Substance Abuse Mental Health Services Administration's (SAMHSA's) *A National Call to Action: Eliminating the Use of Seclusion and Restraint.* One component of this effort was the funding of a curriculum

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and training for health care leaders in six core strategies to prevent and reduce use of seclusion and restraint. The training was created by the National Association of State Mental Health Program Directors' National Technical Assistance Center and was provided to thousands of individuals and many hospitals and mental health leaders in 48 states and territories (4). In 2004 SAMHSA funded three-year incentive grants for eight states to implement alternatives to seclusion and restraint in order to reduce and ultimately eliminate their use. SAMHSA renewed this effort in 2007 and recently awarded eight new states three-year grants toward the same goal.

Consistent with the federal direction, some states made regulation changes and ushered in new safeguards that contributed to the reduced use of seclusion and restraint (4,5). Pennsylvania changed its regulations three times during a multiyear effort. Three of its state hospitals stopped using seclusion and restraint, and the goal is for all Pennsylvania state hospitals to attain this status (4,5).

Massachusetts promulgated new prevention-focused standards applicable to all psychiatric facilities in order to advance the significant statewide reductions in seclusion and restraint that were attained through the state's child and adolescent inpatient initiative (5). These new regulations, Prevention of Seclusion and Restraint and Requirements When Used, were created with a public health prevention framework to educate staff about trauma, consumers' experience of seclusion and restraint, and risks associated with their use; anticipate behavioral crises; create person-centered strategies, sensory interventions, and alternatives to containment; rigorously debrief on episodes that occur; and reduce and strive to eliminate the use of seclusion and restraint.

The new regulations prohibit the use of mechanical restraint among children, require trauma assessments and individual crisis planning for every person in a psychiatric unit or facility, and mandate every facility to create a plan to reduce the use of seclusion and restraint. The maximum duration of adult restraint and seclusion that can be ordered was reduced from four hours to two hours, with the intent to reduce the order duration to one hour in 2007 (Childs E, personal communication, Dec 27, 2005). Since implementation, additional statewide reductions have occurred, and the duration of adult episodes of seclusion and restraint decreased more than 50% (4). Beyond these states, many facilities have reported significant reductions, some have successfully replaced seclusion and restraint with alternatives, and others have explicitly cited the Interim Final Rule as a catalyst for decreased use of these practices (4,6).

The new challenge

However, a new challenge to the national effort has emerged. In January 2007 CMS's Final Rule governing patients' rights went into effect (7). The Final Rule appears to move to a centrist position, dilute previous protections, focus on "safe" seclusion and restraint practices despite identifying their risks, and ultimately retreat from the standard-setting high ground claimed during the seven years the Interim Final Rule was in place. Changes are apparent in several areas.

First, the Final Rule seems to focus more on the seclusion and restraint task itself and how to correctly identify what is and what is not seclusion and restraint. A new single standard combines use of these practices for acute, medical, and behavior management purposes and explicitly articulates and adopts the restraint and seclusion definitions established by the Children's Health Act.

Second, there is concerted attention on conducting seclusion and restraint "properly and safely" through new staff training standards and specific practice competencies. Oddly, these standards do not apply to physicians, who have the greatest authority, responsibility, and liability for each event and its outcome. CMS acknowledges that physicians generally do not receive training in use of restraint and seclusion, but the Final Rule requires only that physicians receive a "minimum level of training" and leaves the determination of sufficient training to hospital-specific policy. Also, it appears that the Final Rule may be tacitly endorsing a specific training program, because it cites a specific seclusion and restraint training provider, as well as the provider's requirements and Web site. In addition, as part of the implementation burden estimate, the Final Rule lists the fees charged by the provider.

Third, despite a new staff education standard that includes training on how to recognize physical distress and monitor physical well-being, the Final Rule abandoned certain monitoring requirements and now "provides flexibility for trained staff to determine the monitoring parameters necessary when a restraint or seclusion is used" and allows hospital policy to guide the extent of monitoring. The Interim Final Rule's important "one-hour rule" standard—which elevated the medical oversight of these procedures by mandating assessment by a physician or a licensed independent practitioner within one hour of episode initiation—was also diluted. The Final Rule now allows registered nurses and physician assistants to perform this assessment (7). Although CMS proposed to augment the diminished one-hour standard by creating an independent review committee to scrutinize practice and reinstate the requirement of having a physician or licensed independent practitioner provide oversight if violations in these practices occurred, these changes never materialized (8).

Fourth, and most ironic, nowhere in the Final Rule does the concept of specifically preventing the use of seclusion and restraint ever appear. Moreover, the recommendation to require debriefing, a critical tertiary prevention strategy, was rejected and described by CMS as "impractical" and "unnecessary," which is contrary to basic root cause analysis procedures used when a sentinel event such as a death or serious injury occurs. However, the Final Rule does anticipate death related to seclusion or restraint and identifies new requirements, also based on the Chil-

dren's Health Act, regarding event-related death reporting.

It appears that CMS ultimately yielded to some of the most influential stakeholders who were among the 4,200 Interim Final Rule commenters, including the American Medical Association, the American Psychiatric Association, the American Hospital Association, and the National Association of Psychiatric Health Systems. These provider groups not only lobbied against the Interim Final Rule, but the latter two organizations also challenged the "one-hour rule" in federal court and attempted to block its implementation (8). In addition, the Joint Commission followed CMS's lead and revised its standards in May 2007 to align with the Final Rule's modified one-hour rule.

It is not clear why these agencies weakened the very regulations that they created and implemented several years ago. Regulatory backsliding impedes SAMHSA's national goal of eliminating seclusion and restraint and thwarts CMS's objective to reduce use of restraint and seclusion and their associated deaths. By lowering the critical physician oversight and assessment requirement, these standard-bearing organizations also heightened the risk to consumers by not having the greatest degree of medical oversight available at the earliest possible moment during declared emergent conditions while the most lethal practice in psychiatry is in use. Moreover, retreating on the one-hour rule compromises future efforts to change regulations at the local level by restoring certain past practices. Now, some state regulatory change efforts have stalled, and other states, such as Texas, are currently considering broadening the parameters related to licensed independent practitioners so that lesser-trained professionals will be allowed to perform assessments of consumers in restraint or seclusion (9).

Since the *Hartford Courant* exposé and initial changes in national standards, the mental health field has learned a great deal about preventing treatment violence and reducing the use of seclusion and restraint (4–6). The failure to recognize these advances and incorporate this knowledge into the new standards not only threatens practice gains but also has spurred legal advocates to analyze the impact of this change, examine federal statutory language, and consider challenging this regulatory retreat (Huckshorn K, personal communication, March 19, 2007).

Local leadership

In a quality improvement model, states and facilities must not rely on national standard-setting entities to lead change toward preventing and even eliminating seclusion and restraint. Regulations are minimum standards. Nothing precludes a state, facility, or treatment program from implementing more stringent requirements. A number of facilities have unilaterally advanced their practice by significantly decreasing the maximum duration of an order for seclusion and restraint, by requiring on-site physician review before medication restraint is administered, and by obtaining additional physician consultation before seclusion or restraint renewals are considered (4).

Ultimately, advancing seclusion and restraint standards is in the hands of facility and agency administrators. The knowledge about how to do this work is available, but it takes leadership, courage, and effort. Unless local leaders accept this challenge, it is possible that the national vision of eliminating seclusion and restraint has been sunset by the agency that boldly raised the standards to a higher level. Without forthright, consistent leadership to elevate practice standards, the possibility of seclusion and restraint "regulatory scotoma" looms large—that is, the possibility of medicine's forgetting established advances as though they never existed (10).

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