

Title 25. Health Services

Part 1. Department of State Health Services

Chapter 415. Provider Clinical Responsibilities

Subchapter F. Interventions in Mental Health Programs

Repeal - Division 1. General Provisions, §§415.521 - 415.257

Repeal - Division 2. Restraint or Seclusion Initiated in Response to a Behavioral Emergency, §§415.261 - 415.274

Repeal - Division 3. Restraint During Certain Procedures, §415.285

Repeal - Division 4. Procedures That Are Not Restraint or Seclusion, §§415.290 - 415.292

Repeal - Division 5. References and Distribution, §415.299 and §415.300

New §§415.251 - 415.276

DRAFT -- Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (DSHS), proposes the repeal of §§415.521 - 415.257, 415.261 - 415.274, 415.285, 415.290 - 415.292, 415.299 and 415.300, and new §§415.251 - 415.276, concerning interventions in mental health programs.

BACKGROUND AND PURPOSE

The purpose of this subchapter is to describe requirements for ensuring the safe and effective use of restraint and seclusion in certain types of facilities in which mental health services are provided, consistent with the provisions of Texas Health and Safety Code, Chapter 322, concerning Use of Restraint or Seclusion in Certain Health Care Facilities, as amended by Senate Bill 325, 79th Legislature, Regular Session, 2005 (SB 325), and as amended by SB 1842, 83rd Legislature, Regular Session, 2013 (SB 1842). In addition, the new subchapter as proposed incorporates certain changes in terminology and other changes in federal requirements governing the use of restraint and seclusion in hospitals, including psychiatric hospitals, as well as psychiatric residential treatment facilities providing psychiatric services to individuals under age 21. These federal requirements are set forth at 42 Code of Federal Regulations (CFR) §482.13, Conditions of Participation: Patients' rights, and at 42 CFR Part 483, Subpart G - Conditions of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21.

Collectively, the statutory revisions to Health and Safety Code, Chapter 322, require the department to implement, through rule, best practices and procedures intended to reduce, and to ensure the safe use of, restraint and seclusion occurring within facilities subject to the department's jurisdiction; authorize registered nurses to conduct the one hour face-to-face following a restraint or seclusion; require a physician to evaluate the individual face-to-face when an order for restraint or seclusion is renewed; and require facilities to file with the department a quarterly report regarding hospital-based inpatient psychiatric services measures related to the use of restraint and seclusion that is required by the federal Centers for Medicare and Medicaid Services (CMS).

After the adoption of this subchapter the department intends to resume its broader review of the rules contained in this subchapter, to address input it has previously received from the stakeholder community and from others, regarding certain aspects of the rules that are not being changed at this time, due to the legislative requirement that the current rule revisions be made effective no later than January 2014.

SECTION-BY-SECTION SUMMARY

Changes made throughout the subchapter include various grammatical, punctuation, and formatting changes. Also, any references to the “Texas Department of Mental and Mental Retardation” or TDMHMR” have been changed to the “Department of State Health Services (DSHS)” as applicable. Any reference to the term, “patient,” has been replaced with the term, “individual.” Sections within the subchapter have been reorganized to promote clarity, and division designations are deleted. In addition to these overall changes, more specific proposed changes included in the new subchapter are described below.

Section 415.251 states the purpose of the subchapter; incorporates the new CMS COP terminology concerning the use of restraint or seclusion for the management of violent, self-destructive behavior and non-violent, non-self-destructive behavior; and emphasizes the need to reduce the use of restraint and seclusion as much as possible, to ensure that the least restrictive methods of intervention are used, and to ensure that, wherever possible, alternatives are first attempted and determined ineffective. Although this language is not included in current §415.251, relating to “Purpose,” similar language is included in §415.261(a) of the current rules and is being moved to the section related to “Purpose,” as a more logical placement of DSHS’ stated intentions in connection with the use of restraint and seclusion.

Section 415.252 identifies the types of facilities to which the new subchapter applies. Consistent with Health and Safety Code, §241.0265 (concerning Standards for Care for Mental Health and Chemical Dependency), language in this section clarifies that this new subchapter applies not only to an “identifiable mental health service unit” of a hospital licensed under Health and Safety Code Chapter 241, but also to such a facility regardless of where in the facility mental health services are provided, to the extent and as provided by Chapter 133 of this title (relating to Hospital Licensing). In addition, the Texas Center for Disease is added, to the extent that mental health services are provided in that facility.

Section 415.253 sets forth definitions of terms used throughout the subchapter. Definitions are added for the terms, "declaration for mental health treatment," "face-to-face," "initiate," "PRN," "seclusion room," and "treatment team." In addition, the term, "advanced practice nurse," is replaced with the term, "advance practice registered nurse or APRN," consistent with the terminology used by the Texas Board of Nursing in its rules found at 22 TAC Part 11.

Consistent with 42 CFR §482.13, the definition of the term "behavioral emergency" is revised to clarify that a behavioral emergency situation involves an individual who is behaving in a violent or self-destructive manner and in which preventive, de-escalative, or verbal techniques have been attempted and determined to be ineffective or clearly would be ineffective.

The term, "clinically competent registered nurse," is replaced with the term, "registered nurse," and the requirement for clinical competency is added to the definition.

Clarifying language is added to the terms "chief executive officer," "clinical timeout," "continuous face-to-face observation," "emergency medical condition," "physician assistant," "protective device," "staff member," and "treating physician." Consistent with 42 CFR §482.13, revisions are made to the definitions for the terms "mechanical restraint," "personal restraint, and "restraint," except that the use of drugs or medications (chemical restraint) continues to be excluded from the definition of restraint.

Section 415.254 sets forth the general prohibition that restraint or seclusion may not be used, except as provided by this subchapter, and identifies, in subsection (b), the circumstances in which personal or mechanical restraint or seclusion are permissible.

Subsection (c) further prohibits the use of restraint or seclusion unless a facility develops, implements, and enforces written policies and procedures, as well as a staff training program, that are consistent with this subchapter. Additionally, subsection (c)(3) prohibits a facility's use of restraint or seclusion unless staff members of the facility are trained and have demonstrated competence in the use of restraint and seclusion in accordance with the facility's written policies and procedures and training program before assuming direct care duties and before performing restraint and seclusion on the individual.

Subsection (d) requires that a facility notify an individual or the individual's legally authorized representative (LAR) of the facility's policies related to the use of restraint and seclusion. This new language is required by Health and Safety Code, §322.053, enacted by SB 325.

Subsection (e) states that it represents minimum standards and that a facility may, through its written policies and procedures, adopt more stringent standards that are consistent with this subchapter and do not conflict with department rules, state or federal law, or applicable accreditation standards. This language, revised somewhat, is currently found in §415.261(b) of this subchapter.

Section 415.255 describes the prohibited and restricted practices associated with the use of restraint or seclusion. Chemical restraint continues to be a prohibited practice. Language in paragraph (b), which relates to the use of a prone or supine hold, is revised from the language found in current §415.254(i) of this subchapter, and is more restrictive than the current language in that it explicitly prohibits the use of either a prone or supine hold during a restraint. The revised language further states that, should an individual become prone or supine during a restraint, then any staff member involved in administering the restraint shall immediately transition the individual to a side lying or other appropriate position.

Section 415.256 addresses the use of mechanical restraints, and the language of this new section is largely the same as the language of the current rule. In subsection (c), added to the list of prohibited devices, regardless of their commercial availability, is a new paragraph (6), regarding spit hoods, or anything that obstructs an individual's airway, including a device that places

anything in, on, or over the individual's mouth or nose. In subsection (e), strait jackets are removed from the list of approved mechanical devices.

Section 415.257 requires facilities to ensure that all staff members are informed of their roles and responsibilities under this subchapter and that they be trained and demonstrate competence accordingly. Subsection (b) identifies the required elements of a facility's training program, including the requirement that it be standardized throughout the facility; emphasize the importance of reducing and preventing the unnecessary use of restraint or seclusion; be evaluated annually; incorporate evidence-based and best practices; provide information about declarations for mental health treatment.

In addition to requirements already identified in subsections (c) and (d) of the current rule, subsections (c) and (d) include a number of new required elements that must be included in training for all staff members, and in which staff members must demonstrated their competence before assuming job duties involving direct care responsibilities (and before initiating any restraint or seclusion), and at least annually thereafter. The new requirements place a greater emphasis on knowledge and demonstrated competency in skills intended to reduce the number of preventable incidences of restraint and seclusion, such as the use of team work; identifying underlying medical, physical, emotional, cultural, and other factors that may contribute to an incidence of a behavioral emergency; use of de-escalation, mediation, problem solving and other nonphysical interventions such as clinical time out and quiet time; recognition and response to signs of physical distress during restraint or seclusion, including asphyxiation, aspiration, and trauma; and use of restraint or seclusion only as a last resort in a behavioral emergency.

Similarly, language in paragraph (6) of subsection (e), regarding annual training for registered nurses, is changed to require that such training (and demonstrated competency) address providing assistance to individuals in de-escalating a behavioral emergency, including through identification and removal of any known stimuli that may be contributing to the circumstances surrounding the behavioral emergency. This proposed new language substitution eliminates current rule language that arguably places greater responsibility on the individual to *demonstrate* that they meet certain criteria for discontinuing a restraint or seclusion, rather than the development of staff members' knowledge and skills that enable them to assist the individual.

Section 415.258 sets forth the actions to be taken to release an individual from restraint or seclusion in a medical or environmental emergency. The language of this section, which is not changed from the language of current §415.258, addresses how staff members must respond when an individual experiences an emergency medical condition while in restraint or seclusion, as well as how staff members must respond when an emergency evacuation or evacuation drill occurs while an individual is in restraint or seclusion.

Section 415.259 relates to: subsection (a) special considerations a physician must consider before ordering the use of restraint or seclusion for a particular individual; subsection (b) certain staff member responsibilities while an individual is in restraint or seclusion; subsection (c) alternative strategies that must be reviewed, implemented, and documented by an individual's treatment team when an individual's behavior has necessitated the use of a restraint or seclusion at a particular frequency of occurrence or duration; and subsection (d) modification of an individual's

treatment plan, after consultation with the facility's medical director or designee, to address alternative treatment strategies. The language in subsections (a) - (c) is largely unchanged from the language in current §415.261(a)(3) - (12), and includes an additional circumstance in which alternative strategies must be considered by the individual's treatment plan: when an episode of restraint or seclusion has continued for more than the maximum time permitted under §415.261(b), which specifies certain time limitations on orders for restraint or seclusion initiated in response to a behavioral emergency.

Subsection (d), relating to modification of an individual's treatment plan, is new, and requires that an individual's treatment team consult with the facility's medical director (or designee) to explore alternative treatment strategies and a written modification to the individual's treatment plan, in the event that the frequency of occurrence or duration of episodes of restraint or seclusion recurs or continues even after the treatment team has, in accordance with subsection (c), already attempted to identify alternative strategies for dealing with an individual's behaviors that necessitate the use of restraint or seclusion. The addition of subsection (d) is intended to ensure that a facility exhausts all possible avenues, including consultation with the facility's medical director, for identifying alternative strategies and alternative treatment strategies for dealing with an individual's behaviors that necessitate the use of restraint or seclusion, thereby reducing the number of restraints and seclusions at facilities subject to the requirements of this subchapter.

Section 415.260 sets forth the process and responsibilities of staff members for initiating a restraint or seclusion. Much of the language of this section is unchanged from the current language found in §415.262 of this subchapter. However, new language included in this new section, consistent with amendments to Health and Safety Code, Chapter 322 (the addition of a new §322.052, pursuant to SB 1842), authorizes the face-to-face evaluation required in subsection (c) to be conducted not only by a physician, as provided in the current rule, but also by a registered nurse who is trained to assess medical and psychiatric stability with demonstrated competence, other than the registered who initiated the use of restraint or seclusion. In addition, reference to an "advanced practice nurse" is not included in paragraph (4) of subsection (c), as registered nurses are now permitted to conduct a face-to-face assessment without delegation from a physician, and the term, "advanced practice nurse," is included within the broader term, "registered nurse" under the Texas Board of Nursing rules found at 22 TAC §221.1. Finally, paragraphs (3), (5) and (6) of subsection (c) are new. Paragraph (3) states what must be assessed during a face-to-face evaluation. Paragraph (5) requires a physician assistant or registered nurse who has conducted the face-to-face evaluation to contact a physician and request that the physician perform a face-to-face evaluation of the individual when, in his or her professional judgment, the physician assistant or registered nurse determines that there are circumstances outside the physician assistant's or registered nurse's scope of practice or expertise. Paragraph (6) requires the registered nurse or physician assistant to consult the physician who is responsible for the care of the individual as soon as possible after the completion of the one hour face-to-face evaluation, and to document the consultation in the individual's medical record.

Section 415.261 sets forth the time limitations for original orders and renewed orders for restraint or seclusion. These time limits are not changed from those in the current rule, and are consistent with those required by 42 CFR §482.13. This section is revised to incorporate new

requirements established by SB 1842, relating to a physician's renewal of such orders that have not yet expired. A physician is required to conduct a face-to-face evaluation before issuing or renewing an order that continues the use of a restraint or seclusion. In addition, the physician is required to document the clinical justification for continuing the restraint or seclusion before issuing a renewal order.

Section 415.262 requires that the CEO or CEO's designee notify the individual's LAR or an authorized family member of each episode of restraint or seclusion. A new requirement is added to this section, that such notification be provided as soon as possible, but no later than 12 hours following the initiation of the restraint or seclusion, when the restraint or seclusion has involved an individual who is a minor under age 18 and who is not or has not been married. The CMS Conditions of Participation, 42 CFR §483.366(a), require that this notification occur "as soon as possible." The current rule reflects this requirement; however, the department has determined that an outside limit of no more than 12 hours from the initiation of the restraint or seclusion is reasonable and accounts for instances that occur in the middle of the night, when it may be inconvenient for an individual's LAR or authorized family member to be contacted. The new language does not require a facility to refrain from contacting the LAR or authorized family member immediately, but it does allow for an agreed upon time frame, within the 12-hour limitation, to be arranged between the facility and the LAR or authorized family member. The current rule language could be interpreted as not allowing such an agreement to be made. Subsection (b) contains a new requirement that the documentation of such notification include any unsuccessful attempts, the phone number called, and the name(s) of person(s) with whom the staff member spoke. This ensures that the documentation is sufficient to meet the standards set forth in the CMS Conditions of Participation, found at 42 CFR §483.366(b), and better assures DSHS, in its regulatory capacity, that facilities are in fact attempting to notify an LAR or authorized family member by documenting those attempts.

Section 415.263 explains that an individual's right to retain personal possessions and personal articles of clothing may be suspended during mechanical restraint or seclusion. It also describes a process for inventorying, storing, and returning individuals' possessions and clothing. A new requirement, found in subsection (e) of this section, requires that if the individual is unwilling to sign the documentation, a staff member shall document the refusal in the individual's medical record and list the items that were returned to the individual, the time they were returned, and the staff member who returned the items.

Section 415.264 describes the procedures for responding to behavioral emergencies during off-premises transport, excursions off facility premises, restraint initiated prior to transport, or restraint initiated during transport. Subsection (c) of this section clarifies that it applies to a restraint initiated prior to transportation of any sort, not just to transportation to another facility and also recognizes that a restraint can be used not only when criteria for a behavioral emergency are present but also when an individual has been determined to be manifestly dangerous within one month prior to transporting the individual. This change reflects a need to ensure the safety of individuals and staff members involved in such transportation. Concerning comfort during transportation, subsection (c) is changed by deleting reference to the need to provide reasonable opportunities for food, water, and to use the bathroom, and now refers to §415.266(c) of this title (relating to Observation, Monitoring, and Care of the Individual in

Restraint or Seclusion Initiated in Response to a Behavioral Emergency), which includes not only those requirements but also provides for additional requirements for the care of individuals in a restraint or seclusion initiated in response to a behavioral emergency, thus making all of these requirements applicable to transportation of an individual as well.

Section 415.265 describes how to communicate with an individual in restraint or seclusion initiated in response to a behavioral emergency. The section has been changed by adding a requirement that a staff member refer to the individual's declaration for mental health treatment (if any) in determining and implementing an individual's preferences. The section is also changed by requiring the staff member to communicate reassurance and commitment to the individual's safety on an ongoing basis, including inquiring how the staff member can assist the individual in de-escalating. This proposed new language, and the deletion of the current language, emphasizes a more positive and therapeutically appropriate interaction between staff members and individuals in a restraint or seclusion, as well as a more effective means of managing the circumstances surrounding a restraint or seclusion.

Section 415.266 sets forth the requirements for observing, monitoring and caring for individuals while in restraint or seclusion. A staff member is required to maintain continuous face-to-face observation while an individual is in seclusion for at least one hour. After one hour, the staff member may monitor the individual continuously using simultaneous video and audio equipment in close proximity to the individual. In addition to certain changes intended to clarify subsection (c), new language in that subsection describes more specifically the circumstances in which certain care must be provided.

Section 415.267 describes the requirements for the facility to develop and implement policies and procedures to ensure that appropriate techniques are used and the environment is safe when initiating restraint or seclusion. Paragraphs (2) and (3) of subsection (a) include new proposed language that clarifies that the environment in which an individual is restrained to be observable by other staff members and is away from other individuals. A new subsection (b) requires a facility to develop and implement policies and procedures to ensure that it is in compliance with the requirements of this section.

Section 415.268 describes the actions to be taken when an individual falls asleep in restraint or seclusion, which include releasing the individual immediately.

Section 415.269 describes the process for transferring primary responsibility between staff members for an individual in restraint or seclusion, including such a transfer at the time of a shift change. Language added in subsection (a) of this section requires a staff member to monitor the individual during the transfer process. This new language makes it clear that there must be no gap in the responsibility to maintain continuous face-to-face monitoring and the other requirements of a staff member under §415.266 of this title. Language added in subsection (b) requires documentation of the nature of the circumstances requiring restraint or seclusion.

Section 415.270 describes the steps to be taken for the release of an individual from a restraint or seclusion. This new rule, which replaces §415.272 of this title, provides additional detail regarding the procedures to be taken for a personal restraint and those to be taken for a

mechanical restraint or seclusion. The changes distinguish between a personal restraint and a mechanical restraint or seclusion, in that it requires a staff member to release the individual as soon as the unsafe condition has ended, when a personal restraint has been used, but requires that only a physician, physician's assistant, or registered nurse evaluate the individual before a staff member can release the individual who is in a mechanical restraint or seclusion. These changes are consistent with the requirements of S.B. 325, which requires the department to adopt rules to define acceptable restraint holds that minimize the risk of harm to a facility resident, as well as the requirements of the CMS Conditions of Participation.

Section 415.271 describes the actions to be taken following the release of an individual from restraint or seclusion; e.g., facilitating the individual's reentry into the social milieu, observing and documenting the individual's behavior, and debriefing the individual and staff members who are involved. Language is added to paragraph (3) of subsection (a) clarifying that documentation of a restraint or seclusion must be made in the individual's medical record. Language is added to paragraph (5) of subsection (b) to require that appropriate modifications be made not only to the treatment plan of an individual who has been restrained or secluded, but also to the treatment plans of other individuals, when indicated. Language is added to subsections (c) and (d) to require that debriefings with the individual and staff members be conducted following restraint or seclusion, and to specify what must be addressed in the debriefing as well as a timeframe within which the documentation must be completed (within 24 hours after the debriefing is conducted or attempted).

Section 415.272 establishes requirements for facilities to document use of restraint and seclusion and to report restraint and seclusion data to the Department of State Health Services. Subsection (a) requires additional information in the medical record including signatures and identification of roles of staff members present during initiation; the name of the individual and type of restraint or seclusion used; the time and results of observations and monitoring; and other documentation relating to an episode of restraint and seclusion otherwise required under the rule. This subsection as proposed contains a number of new requirements for information that must be documented. Also, certain language has been deleted from this subsection (a), including the deletion of paragraph (4)(B), which requires that an individual's medical record include documentation of other generally accepted less intrusive forms of intervention, if any that the physician evaluated but rejected, and the reasons those interventions were rejected. This documentation requirement has been moved to new §415.260(b)(1)(D) of this title, which describes the types of information that must be documented in the physician's order.

New requirements in subsection (b) include a report to the facility's CEO to address use of restraint or seclusion that is determined or suspected of being improper at the time it occurs; as well as the types and dosages of emergency medications administered during the restraint or seclusion. Paragraph (1) of the subsection includes a new requirement that the CEO or designee take appropriate action to identify and correct unusual or unwarranted utilization patterns on a systemic basis, and to address each specific use of restraint or seclusion that is determined or suspected of being improper at the time it occurs. This will allow the facility to identify and evaluate systemic issues arising from the use of restraint and seclusion, thereby ensuring proper use of restraint and seclusion as well as a reduction of their use. Paragraph (2)(D) is also added, requiring that the facility's central file contain the types and dosage of emergency medications

administered during the restraint or seclusion, if any. This additional data will better inform the CEO's evaluation of systemic issues arising from the use of restraint and seclusion, as required by paragraph (1).

Subsection (c) requires facilities to report data on serious injuries as well as deaths that occur during or after restraint or seclusion. Subsection (c) also adds new provisions defining which deaths to report, including a death that occurs 24 hours after the individual has been removed from restraint or seclusion; and each death known to the facility that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to the patient's death.

Subsection (d) identifies the various entities to which a facility must submit the reports required by subsection (c). This subsection replaces current subsection (c) and also adds a new reporting requirement for facilities licensed under Chapter 133 or Chapter 134 of this title, that a death or serious injury be reported to the Patient Quality Care Unit of DSHS's Division for Regulatory Services.

Subsections (e) and (f) are new provisions. Subsection (e) specifies the review and analysis required by each facility of the data required in subsection (b)(2). Subsection (f) requires the facility to use the data analysis to continually to improve its practices to minimize the use of restraint and seclusion and to ensure the safety of individuals and staff members. These two new subsections require that the facility review and analyze, at least quarterly, the data that is required by subsection (b)(2), and that the facility use this data continuously to ensure: a positive environment, the safety of individuals and staff members, the use of restraint and seclusion is done in accordance with the requirements of this subchapter, reduction of the risks of injury and other negative effects to individuals and staff members, and that policies and training curriculum incorporate the requirements of this subchapter.

Subsections (g) and (h), relating to reporting requirements, are also new and implement the reporting requirements of SB 325 and SB 1842. Subsection (g) requires a facility that is a Medicare or Medicaid provider to submit, on or before November 1, 2014, and quarterly thereafter, the data required by Centers for Medicare and Medicaid Services for hospital-based inpatient psychiatric service measures related to the use of restraint or seclusion. Subsection (h) requires a facility to prepare and submit to DSHS, consistent with the *Department of State Health Services Behavioral Interventions Reporting Guidelines*, certain data related to emergency interventions that occurred during the previous period, including data regarding emergency seclusions, personal restraints, mechanical restraints, and involuntary medication orders, as well as a description of the types of de-escalation techniques commonly used by that facility in connection with any of the emergency interventions used.

Implementation of these reporting requirements allows data regarding the use of restraint and seclusion to be collected and analyzed at the state level, in order to identify trends and any systemic issues that may be impeding the reduction of these interventions within the facilities subject to this subchapter, as recognized by the statement of intent within the Senate Research Center's bill analysis for SB 325. The reporting requirement of SB 1842 also recognizes the value in collecting this data at the state level, and the need to reduce the number of restraints and

seclusions occurring within these facilities, in that the Senate Research Center's bill analysis for SB 1842 acknowledges that use of these interventions jeopardizes the immediate physical safety of individuals, staff members, and others. While SB 1842 focuses specifically on reporting requirements for facilities that are Medicare or Medicaid providers, the additional reporting requirements of proposed new subsection (h) allow data to be reported and analyzed at the state level for all facilities subject to this subchapter, regardless of whether the facility is a Medicare or Medicaid provider.

Section 415.273 consistent with 42 CFR §483.13, the section describes the use of restraint for the management of non-violent, non-self-destructive behavior. This terminology replaces, at various places within this section, as the terminology, "during medical, dental, diagnostic, or surgical procedures," to make the provisions more inclusive of situations that do not constitute a behavioral emergency, not just those involving a medical, dental, diagnostic, or surgical procedure. The addition of language in paragraph (4) of subsection (a) also broadens this section to include situations in which a less restrictive intervention has been attempted and determined ineffective; this change is consistent with other similar changes made throughout this new subchapter. This section also makes clear that restraint used in a medical, dental, or surgical procedure may follow the requirements of restraint in a behavioral emergency instead of this section if the reason for the restraint is to manage an individual's violent, self-destructive behavior, even during a medical procedure.

A new subsection (d) of this section addresses the physician's renewal of an order for restraint, which may be done as frequently as determined by facility policy, but requires that the time period covered by an order be longer than 24 hours.

Subsection (f), which replaces subsection (e) of the current rule, includes among the criteria to be assessed in a facility's policies and procedures an additional physical status (cardiac function) that must be assessed in an individual who is being restrained.

Subsection (g) replaces subsection (f) of the current rule, and adds clarifying language to indicate that it applies to any contractor providing dental services on the facility premises. In addition, it requires that the dentist maintain a copy of the order in the individual's medical record and shall ensure compliance with the requirements of the order.

Section 415.274 describes permitted practices that may occur and that are not considered restraint (i.e., escort or brief physical prompt; activities of daily living; immobilization during medical, dental, diagnostic, or surgical procedures). Subsection (c) is added to allow a staff member to escort, prompt, or move an individual who is unable to respond in the affirmative or negative or is unable to move due to his or her psychiatric condition if there is an imminent danger of harm to the individual because of a circumstance in the individual's immediate environment. This new language ensures an individual's safety and well-being while balancing the individual's independence with their right to be reasonably protected from harm.

Language is added to subsection (d) to require the individual's consent for use of any positioning or securing device used during medical, dental, diagnostic, or surgical procedures that are not a standard part of the procedure. Subsection (d) of the current rule, relating to the administration

of psychoactive medication under court order or in an emergency, is deleted. This change brings the rule into conformity with the CMS Conditions of Participation, which explicitly define a “personal restraint” to not include a “brief physical hold.”

Section 415.275 establishes criteria for the use of clinical time out and requires that the facility develop and implement policies and procedures that are consistent with the criteria. Language is added to subsection (b)(2)(A) and (B), providing that when a staff member requires an individual to remain in quiet time after the individual has indicated a desire to terminate any self-initiated quiet time, the situation becomes a restraint and/or seclusion, as applicable, and becomes subject to the requirements for restraint described in this subchapter. Paragraph (2)(B) of the subsection is further modified by the addition of language explicitly stating that under no circumstances, except for clinical reasons, may a facility staff member coerce or force a client out of quiet time. These changes make it clearer that quiet time is a voluntary step taken by an individual, and that any so-called quiet time that is imposed by a staff member is not voluntary, and therefore constitutes a restraint and/or seclusion. The changes also bring the language of paragraph (2), concerning quiet time, into conformity with the language of paragraph (1), concerning clinical timeout.

Section 415.276 describes the proper use of protective and supportive devices. Changes in the language of this section, which is currently found in §415.292 of this subchapter (related to Protective and Supportive Devices), are proposed for better readability and clarification purposes.

FISCAL NOTE

Mike Maples, Assistant Commissioner for the Mental Health and Substance Abuse Division, has made the following determinations, for each year of the first five-year period that the proposed new subchapter will be in effect:

There will be no additional costs to state or local governments as a result of enforcing and administering the sections as proposed. With respect to the state hospitals, state centers, Waco Center for Youth, and TCID, Mr. Maples does not anticipate any costs related to enforcing or administering the proposed new subchapter. Should there be more language in this section, about costs to DSHS Regulatory Division as a result of enforcing the new sections? Any additional outlay for receiving the data that must be reported by the 133 and 134 facilities? Any anticipated costs related to enforcement of these new rules against the licensed facilities? If so, need to revise first sentence above, and need to add language here, describing the estimated costs. If not, please leave first sentence “as is,” and delete second sentence (re: state-operated facilities).

To the extent that implementation of the proposed new rules results in a reduction in the number of restraints and seclusions, there will be a reduction in costs to state and local governments, in that the state hospitals, the Waco Center for Youth, the Texas Center for Infectious Disease, and community mental health service providers to which the proposed new sections would apply, will see a reduction of costs associated with treatment of injuries sustained by staff members, individuals, and others who may be involved in a restraint or seclusion. Until trends and

systemic issues can be identified and addressed as a result of the data collected and analyzed by the department and by HHSC pursuant to §415.272(g) and (h), the cost savings cannot be precisely determined.

No loss or increase in revenue to state or local governments is anticipated as a result of enforcing or administering the proposed new sections.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mike Maples, Assistant Commissioner of the Mental Health and Substance Abuse Division, has determined that the proposed rules will have no adverse economic effect on small businesses or micro-businesses, as those entities are defined by Government Code §2006.001. Small businesses and micro-businesses will not be impacted will not be required to alter their business practices in order to comply with the proposed sections. There is no anticipated negative impact on local employment.

PUBLIC BENEFITS AND COSTS

In addition, Mr. Maples has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the proposed new sections. The public benefit anticipated as a result of the new sections will be the expansion of the number and types of health care professionals authorized to perform face-to-face evaluations, to include an appropriately trained and licensed registered nurse, thus bringing the standard in Texas into conformity with the CMS standard for identify those who are authorized to perform such evaluations of an individual to assess his or her medical and psychiatric stability within one hour of the initiation of the restraint or seclusion. The public will also benefit from a reduction in the use of restraint and seclusion in facilities where mental health services are provided and, therefore, the reduction in the number of potential injuries sustained by individual and staff members involved in a restraint, or by others who are in close proximity to a restraint, whose physical safety may be jeopardized by the restraint. The public will also benefit by the fact that, to the extent that a restraint or seclusion is used within a facility subject to these new rules, the least restrictive methods of intervention will be used and, wherever possible, alternatives will first be attempted or determined to be ineffective. Finally, the public will benefit from the new reporting requirements, which will allow data regarding the use of restraint and seclusion to be collected and analyzed at the state level, in order to identify trends and any systemic issues that may be impede the reduction of such interventions within the facilities that are required to comply with the new sections as proposed.

Mr. Maples also anticipates that, for each year of the first five-year period that the proposed new sections will be in effect, there are probable economic costs for persons required to comply with the rules, primarily with respect to the new reporting requirements. It is anticipated that facilities that are not already reporting to DSHS (psychiatric hospitals licensed pursuant to Health and Safety Code, Chapter 577; hospitals licensed pursuant to Health and Safety Code, Chapter 241, providing mental health services; and crisis stabilization units licensed pursuant to Health and Safety Code, Chapter 577), which will be required to comply with the new documentation, reporting, and analysis requirements of §415.272, may incur a one-time computer programming

cost, to the extent that such programming is needed to enable a facility to document and report the data required by §415.272. This cost would be incurred during the first or second year the new sections are in effect, in anticipation of the dates (November 1, 2014, and November 1, 2015, respectively) on which the reporting activities will be required to commence. The cost per hospital is estimated to be between \$,4000 to \$8,000 (based on an estimated cost of hiring a programmer at the rate of \$200 per hour, and for an estimated time frame of between 20 to 40 hours to complete the programming work). Mr. Maples anticipates that the cost per hospital would be less than this estimated range, for hospitals or other facilities that are part of a hospital system of two or more hospitals, to the extent that such a system incurs the programming costs on behalf of multiple hospitals within that hospital system.

In addition to the estimated costs associated with reporting requirements, described above, costs associated with development and delivery of additional training necessary to ensure compliance with the new sections may be incurred by facilities required to comply with the new sections. To the extent that any new or revised training or curriculum content will be required, the state-operated facilities will make any necessary changes to its existing courses through their usual process of updating training, thereby minimizing any costs associated with making the revisions, which are estimated to be minimal.

The state-operated facilities will incorporate the new CMS terminology concerning the use of restraint or seclusion for the management of violent, self-destructive behavior and non-violent, non-self-destructive behavior into their hospital policies as a part of their annual policy review process. The change which authorizes the face-to-face evaluation to be conducted not only by a physician, but also by a registered nurse trained to assess medical and psychiatric stability with demonstrated competence, other than the registered nurse who initiated the use of restraint or seclusion, will be accomplished with current registered nurse staff members with no anticipated need for additional registered nurse staff members. The requirement for a physician to conduct a face-to-face evaluation before issuing a renewal order will be accomplished with current physician staff members with no anticipated need for additional physician staff members. These facilities are already complying with the reporting requirements related to restraint and seclusion and no additional costs are anticipated to ensure continued compliance with these requirements.

Mr. Maples anticipates that there will, likewise, be minimal costs incurred by the other, non-state operated facilities required to comply with the new sections, related to updating policies, training, and curriculum content, as well as implementing the utilization of appropriately trained registered nurses to perform face-to-face evaluations, and requiring current physician staff members to perform face-to-face evaluations before issuing renewal orders for restraint or seclusion.

There will be fewer costs, still, for community mental health service providers, and their subcontractors, which are subject to the requirements of Chapter 412, Subchapter G, of this title, which prohibits the use of seclusion by such providers. In addition, these providers generally do not utilize personal restraint in managing violent or self-destructive behavior, as law enforcement is often present during such situations, and are able to intervene and transport the individual to a facility where the individual can receive appropriate mental health treatment. As a result of the relatively limited potential for the use of personal restraints in community settings during a

behavioral emergency, or the use of mechanical restraints by community mental health service providers, Mr. Maples anticipates that the community mental health service providers will incur only nominal costs related to compliance with the new sections, including the new reporting and training requirements.

Mr. Maples does not anticipate that the proposed new sections will affect a local economy.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Janet Fletcher, Program Services Section, Program Design Unit, Department of State Health Services, P.O. Box 149347 (Mail Code 2018), Austin, Texas 78714-9347, or by email to janet.fletcher@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The repeals and new rules are authorized by Texas Health and Safety Code, Chapter 322, governing the use of restrain and seclusion in certain health care facilities; Texas Health and Safety Code, §577.010, concerning rules and standards for the proper care and treatment of patients in private psychiatric hospitals or mental health facilities; Texas Health and Safety Code §13.004, which authorizes the department to transfer to the Texas Center for Infectious Disease an individual who is mentally ill and who is infected with tuberculosis; and Texas Government Code, §531.0055, and Texas Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies

necessary for the operation and provision of health and human services by the department and for the administration of Chapter 1001, Texas Health and Safety Code.

The repeals and new rules affect Texas Health and Safety Code, Chapters 13, 322, 577, and 1001; and Texas Government Code, Chapter 531.

Sections for repeal.

Division 1. General Provisions.

§415.251. Purpose.

§415.252. Application.

§415.253. Definitions.

§415.254. Prohibited Practices.

§415.255. Actions to be Taken in an Emergency While an Individual is in Restraint or Seclusion.

§415.256. Mechanical Restraint Devices.

§415.257. Staff Training.

Division 2. Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.261. General Principles for the Use of Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.262. Initiating Restraint or Seclusion in a Behavioral Emergency.

§415.263. Time Limitation on an Order for Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.264. Family Notification.

§415.265. Disposition of Personal Possessions During Mechanical Restraint or Seclusion.

§415.266. Restraint in Response to a Behavioral Emergency Occurring Off Facility Premises or During Transportation.

§415.267. Communicating Criteria for Release and Releasing the Individual from Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.268. Observation,, Monitoring, and Care of the Individual in Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.269. Safe and Appropriate Techniques for Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.270. Actions to be Taken When an Individual Falls Asleep in Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.271. Transfer or Primary Responsibility for Patient in Restraint or Seclusion.

§415.272. Release of an Individual from Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.273. Actions to be Taken Following Release of an Individual from Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

§415.274. Documenting and Reporting Restraint or Seclusion Initiated in Response to a Behavioral Emergency.

Division 3. Restraint During Certain Procedures.

§415.285. Restraint as Part of Medical, Dental, Diagnostic, or Surgical Procedures.

Division 4. Procedures that are Not Restraint or Seclusion.

§415.290. Permitted Practices.

§415.292. Protective and Supportive Devices.

Division 5. References and Distribution.

§415.299. References.

§415.300. Distribution.

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