Department of Mental Health Testimony to

House Human Services Committee

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Thank you for the opportunity to come before the committee to discuss these three important concerns raised by the Mental Health Oversight Committee.

1. *To whom do the rules on emergency involuntary procedures apply?*

From the Department of Mental Health's perspective it is important to have uniform standards that all hospitals can follow.

All Vermont hospitals are certified by the Center for Medicare and Medicaid Services (CMS) and are therefore required to comply with federal regulations regarding emergency involuntary procedures. In 2007, when CMS promulgated a final revision to the rule for emergency involuntary procedures, they made an important update to indicate that seclusion and restraint regulations were an important patient rights matter and as such should not vary from location to location within the hospital. That is, regardless of where a patient is in a hospital, the same federally-mandated rules apply. All Vermont hospitals, as CMS-certified facilities, abide by these regulations. Their staff members are trained to know and to follow these rules.

CMS provides guidance for how the emergency involuntary procedures are to be applied:

> *The patient protections contained in this standard apply to **all hospital patients** when the use of restraint or seclusion becomes necessary, regardless of patient location. The requirements contained in this standard are not specific to any treatment setting within the hospital. They are not targeted only to patients on psychiatric units or those with behavioral/mental health care needs. Instead, the requirements are specific to the*

patient behavior that the restraint or seclusion intervention is being used to address.

In summary, these restraint and seclusion regulations apply to:

- *All hospitals (acute care, long-term care, psychiatric, children's, and cancer);*
- *All locations within the hospital (including medical/surgical units, critical care units, forensic units, emergency department, psychiatric units, etc.); and*
- *All hospital patients, regardless of age, who are restrained or secluded (including both inpatients and outpatients),.*

Following the passage of Act 79, the Department initiated a rule-making process to establish standards for the use and reporting of emergency involuntary procedures. A side-by-side comparison of the elements of the CMS regulations with the former state hospital's policy is attached.

2. *Who can prescribe chemical restraint?*

The Department of Mental Health recommends that Physicians and Licensed Independent Practitioners (LIPs), with appropriate training in inpatient psychiatric care, be able to authorize Emergency medications when needed.

The prescription of chemical restraint includes the following general steps:

a. Assessment of the emergency i.e. the imminent danger posed by the patient
b. Assessment of how to ensure safety immediately
c. Assess what method is the best ensure safety (EIP or otherwise)
d. If chemical restraint is the best method of safety in a particular circumstance, then a decision has to be made about which medication.
e. Patients history and recent presentation including diagnosis
f. Medications patient is currently prescribed and taking
g. Other comorbidities e.g. COPD or neurological or cardiac disorders
h. Route of administration of medication being considered and its suitability
i. Anticipated benefit

j. Anticipated risk
k. Anticipated drug-drug or drug-food interaction
l. Follow up needed after administration of medication

These complex steps require advanced background knowledge if the subject matters and experience with the administration of these medications. Although these decisions need to be made very quickly and are complex, the steps are not dissimilar to any prescription.

Vermont law allows Physicians, Advance Practice Nurses (APRNs) and Physicians Assistants, under the supervision of a physician to prescribe medication. The scope of licensure is based on the training they receive and the experience they gain to monitor medical condition, knowledge of the illness being treated and pharmacology.

Furthermore, hospitals by way of credentialing, do not allow every practitioner to practice anything they are licensed to practice. Credentialing restricts a practitioner to the area of their specialty. For example, a cardiologist without additional qualification will not be allowed to perform cardio-thoracic surgery. Similarly for inpatient psychiatric units the practitioners who are allowed to provide inpatient care have met the criteria established by the Medical Staff Organization. The Medical Staff Organization credentials all licensed independent practitioners.

Thus the Physicians & LIPs working on inpatient units have extra training that allows them to practice with the specialized knowledge and experience needed to care for patients safely.

3. *Must the prescriber personally observe the patient prior to prescribing chemical restraint?*

The current scope of practice for Physicians and LIP's does not limit the medical professional's prescriptive authority to only those situations where the medical professional personally observes a patient prior to prescribing medication. With regard to parity in the acute health care setting, the prescribing of medication for a medical condition is determined based on the observations and findings of those clinicians present at the time of the needed medical intervention. Current medical practice standards do not establish arbitrary limits for the prescribing of a sub-set of medications for a sub-set of the hospitalized patients.

Inpatient psychiatric care units are designed to work in a team model the same as other areas of inpatient medicine. A typical inpatient care team includes nurses, mental health workers, social workers, psychologists and the psychiatrist or LIP serves as the team leader. Hospital care, as you all know, is designed for 24 hours, seven days a week observation and treatment planning. No one person can observe the patient all of the time. This necessitates information being shared and exchanged at regular intervals both between the same specialty (nurses, social workers etc.), but also across specialties. In other words, the teams are used to relying on each other's observations and knowledge to work with the patient.

This exchange of information also applies to an emergency situation. It's unusual for a physician or LIP to witness the emergency as it happens on an inpatient unit. When the physician is called either in person or by phone, they are relying on the observation made by trained nurses and mental health professionals. In the vast majority of cases this process can be completed by the staff members that are on the unit serving as the eyes and ears for the physician or LIP to make a determination for emergency medications. In other inpatient scenarios, when there are additional complications, the physician or LIP may need to come in.

This has been the standard of care for CMS-certified and/or TJC accredited hospitals across the country for many, many years as well. Other than the former Vermont State Hospital, this has been the standard of practice of all inpatient psychiatric units in Vermont for years.

Emergency Involuntary Procedures Standards
CMS Regulations vs. VSH policy

No.	Standard	CMS	VSH	Differences
1	All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.	✓	✓	
2	Definitions. (i) A restraint is— (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely	✓	✓	
3	A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition	✓	✓	
4	A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).	✓	✓	
5	Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.	✓	✓	
6	Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.	✓	✓	
7	The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.	✓	✓	
8	The use of restraint or seclusion must be -- (i) in accordance with a written modification to the patient's plan of care.	✓	✓	
9	The use of restraint or seclusion must be --] §482.13(e)(4)(ii) - implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law	✓	✓	

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10	The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §481.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.	✓	✓	
11	Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).	✓	✓	
12	The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion	✓	✓	
13	Unless superseded by State law that is more restrictive -- (i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours: For adults, the physician may authorize additional restraints up to two (2) hours which may be administered consecutively without consultation with the physician, but only after the registered nurse (RN) reviews and documents the continuing emergency necessity for an additional time period. No more than two (2) consecutive restraints, or four (4) hours in total, may be ordered without consultation with and personal observation by the physician. Each twenty-four (24) hour period and with continuation of an emergency condition, the physician must see and assess the patient before issuing new written orders for emergency restraint. (A) 4 hours for adults 18 years of age or older; (B) 2 hours for children and adolescents 9 to 17 years of age; or (C) 1 hour for children under 9 years of age; and	✓	✓*	VSH policy called for renewal orders after two hours but can be renewed without a new assessment by physician
14	After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient	✓	✓	
15	Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.	✓	✓	

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16	Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.	✓	✓	
17	The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.	✓	✓	
18	Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.	✓	✓	
19	When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention -- (i) By a – (A) Physician or other licensed independent practitioner; or (B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.	✓	✓*	VSH Policy seclusion and restraint matched CMS but for Emergency Medication required a physician to do the face to face exam
20	The patient must be seen face-to-face within 1 hour after the initiation of the intervention §482.13(e)(12)(ii) To evaluate – (A) The patient's immediate situation; (B) The patient's reaction to the intervention; (C) The patient's medical and behavioral condition; and (D) The need to continue or terminate the restraint or seclusion	✓	✓	
21	§482.13(e)(14) - If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) as soon as possible after the completion of the 1 hour face-to-face evaluation.	✓	✓	

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22	All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored – (i) Face-to-face by an assigned, trained staff member; or (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.	✓	✓	
23	When restraint or seclusion is used, there must be documentation in the patient's medical record of the following: (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;	✓	✓	
24	[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] §482.13(e)(16)(ii) - A description of the patient's behavior and the intervention used.	✓	✓	
25	[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] §482.13(e)(16)(iii) - Alternatives or other less restrictive interventions attempted (as applicable).	✓	✓	
26	[When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] §482.13(e)(16)(iv) - The patient's condition or symptom(s) that warranted the use of the restraint or seclusion.	✓	✓	
27	When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:] §482.13(e)(16)(v) - The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.	✓	✓	
28	Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.	✓	✓	

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29	Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion – (i) Before performing any of the actions specified in this paragraph; (ii) As part of orientation; and (iii) Subsequently on a periodic basis consistent with hospital policy.	✓	✓	
30	Training Content. - The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following: (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.	✓	✓	
31	The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] §482.13(f)(2)(ii) - The use of nonphysical intervention skills.	✓	✓	
32	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] §482.13(f)(2)(iii) - Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.	✓	✓	
33	The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] §482.13(f)(2)(iv) - The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).	✓	✓	
34	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] §482.13(f)(2)(v) - Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.	✓	✓	
35	Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.	✓	✓	

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36	[The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] §482.13(f)(2)(vii) - The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification	✓	✓	
37	Trainer Requirements. - Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors	✓	✓	
38	Training Documentation. - The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed	✓	✓	
39	Standard: Death Reporting Requirements: - Hospitals must report deaths associated with the use of seclusion or restraint. (1) The hospital must report the following information to CMS: (i) Each death that occurs while a patient is in restraint or seclusion. (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion. (iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. “Reasonable to assume” in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. (2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. (3) Staff must document in the patient's medical record the date and time the death was reported to CMS.	✓	✓	

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40	A. If, on the basis of personal observation, any VSH staff member believes an emergency exists with respect to a patient, a physician shall be consulted immediately. B. The physician shall personally examine the patient. C. The physician shall determine whether such facts exist with regard to the patient which necessitates his/her emergency involuntary medication. (The required facts are specified in the "Certificate of Need" form (PN-04-05). D. If, after personal observation of the patient, and only if emergency medication is found to be necessary, the physician may order the involuntary administration of medication, as set forth in I, above. Orders for emergency medication shall not be written as a PRN, telephone or standing order. E. A physician shall assess the patient within one hour of the administration of the emergency involuntary psychotropic medication. F. A physician shall report the emergency involuntary medication of the patient to the Medical Director or physician designated to receive such reports on weekends or holidays, within twenty-four (24) hours		✓*	VSH policy limited the ability to order emergency involuntary medications to physicians only but allowed LIPs to authorize seclusion and manual/mechanical restraint. CMS does not limit LIPS from authorizing involuntary medications
41	On the next working day following an order of seclusion, the Medical Director or his/her designee shall review any orders for seclusion of the patient. If a patient is secluded for more than ten (10) hours in any twenty-four (24) hour period, or for more than twenty-four (24) hours in any five (5) day period, the staff shall report the case at the next patient-oriented meeting and submit a written report to the Medical Director, and the Commissioner of Mental Health, both of whom shall review the Certificate of Need (PN-04-05) and other documentation for adequacy.		✓*	CMS regulations do not call for this however they do require a review as listed in section 13 of this document
42	For any patient placed in seclusion more than three times in any four-week period, the patient's treatment team shall, within three business days, review , and modify as appropriate, the individual's treatment plan		✓*	CMS policy does not address this specific requirement but most hospitals do treatment plan reviews
43	With the patient's consent, the nearest relative or guardian of the patient shall be notified of emergency involuntary administration of seclusion within twenty-four (24) hours of its first use. Counsel shall be notified and provided with a copy of the Certificate of Need (PN-04-05) within twenty-four (24) hours.		✓*	CMS policy does not specify calling of a relative or guardian in this regulation but guardians are expected to be decision makers.

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CMS Regulations vs. VSH policy

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44	Use of physical force to control a patient who is resisting the administration of involuntary psychotropic medication. The involuntary restraint of a patient by any means may be ordered only after personal observation of emergency circumstances by a physician; or in the physician's absence, a registered nurse (RN). Within one hour of the initiation of the emergency safety intervention, individuals placed in restraint shall be assessed by a physician. This assessment must occur face to face and shall include but not be limited to an assessment of: (1) the individual's physical and psychological status; (2) the individual's behavior; (3) the appropriateness of the intervention measures; and (4) any complications resulting from the intervention.		✓*	CMS regulations do not restrict this to physicians only. See section 10. CMS refers to Emergency Medication as chemical restraint and is covered in restraint regulations.
45	Medical Director Review: The Medical Director shall review all orders of emergency involuntary medication, seclusion and restraint at least once every thirty (30) days and shall prepare a report to the Commissioner of Mental Health, the Executive Director and the Treatment Review Panel		✓*	CMS regulations do not cover this but six core strategies calls for close administrative review of all emergency involuntary procedures