October 28, 2016

Commissioner Monica Bharel

Department of Public Health

250 Washington Street

Boston, MA 02108

**Re: Clinic Regulatory Review**

Dear Commissioner Bharel,

The Betsy Lehman Center is pleased to submit observations and recommendations in support of the Department of Public Health’s (DPH) clinic regulatory review process.

The comments contained in the attached table pertain to the reporting of adverse events by clinics under 105 CMR §§ 140.307-140.308. They mainly suggest ways in which DPH might clarify or streamline clinic reporting responsibilities. We believe that these modifications, together with the amendments already proposed by DPH, will lead to more complete adverse event reporting and ultimately enhance DPH’s ability to investigate or intervene as needed. In addition to supporting DPH’s important regulatory function, it is our view that more effective reporting will bolster the facilities’ own internal safety and quality improvement activities and, ultimately, the Commonwealth’s broader health care cost, quality, and transparency goals.

We want to commend DPH on the tremendous effort that has been devoted to the regulatory review process, and thank you for the opportunity to contribute to the discussion.

Sincerely,



Barbara Fain, JD, MPP

|  | **Regulation(s)** | **Observation** | **Recommendation** | **Notes** |
| --- | --- | --- | --- | --- |
| **SREs** |
| **1** | 105 CMR § 140.308(A) | **SRE definition**Under DPH guidance, hospitals and ASCs must report SREs involving their patients that have occurred at other hospitals or ASCs1. However, the present regulatory definition of “SRE” in 105 CMR § 140.308 refers only to events that occur on the premises of hospitals. [Circular Letter #12-9-570 (Sept. 7, 2012)](http://www.mass.gov/eohhs/docs/dph/quality/hcq-circular-letters/2012/dhcq-1209570.pdf) | **Clarification: Standardize SRE definition across hospital and clinic regulations as follows:**[140.308(A)]*“Serious Reportable Event (SRE) means an event that occurs on premises covered by* ***the license of a hospital or ASC*** *~~an ASC’s license~~ that results in an adverse patient outcome…”*  |  |
| **2** | 105 CMR § 140.308 (B)(1)(b)  | **Form of patient notification (7-day)**First, proposed amendments to ASC provisions regarding 7-day patient notification make the clinic SRE regulations inconsistent with hospital regulations. * The proposed clinic regulations 140.308 (B)(1)(b) no longer include the phrase “verbally and in writing”:

 *“(****b****~~c~~) inform the patient or the patient’s representative ~~verbally and in writing~~ about:”** Whereas hospital regulations 130.332(B)(1)(b) read:

 *“(****b~~c)~~*** *inform the patient or the patient’s representative ~~and~~* ***or*** *in writing about:”*Second, assuming the phrase is reinserted, the 7-day patient notification provision still: 1. Uses the word “verbally”—which is inclusive of words both written or oral—rather than the intended word “orally”
2. May imply that the options are mutually exclusive.
 | **Reword 7-day patient notification provision for clarity and emphasis as follows:**[140.308(B)(1)(b)]*(****b~~c)~~*** *inform the patient or the patient’s representative* ***orally*** *~~verbally~~ ~~and~~* ***or*** *in writing* ***or both*** *about:* | The Betsy Lehman Center has received a wide range of input from patients and other stakeholders regarding patient preferences for how information is communicated following an SRE. Because individual needs vary, no notification policy is ideal for everyone. However, we believe that best practice is for facilities to always start with a conversation, followed by a written communication that is appropriate to the situation at hand. We suggest that this principle be conveyed in Departmental guidance if not in the regulation itself. |
| **3** | 105 CMR § 140.308 (B)(1)(c) | **Editing error - Patient notification (7-day)**Citation [140.308 (B)(1)(c)] in clinic SRE regulations was not updated after the line before it, which it references, was revised:*(****b~~c)~~*** *inform the patient or the patient’s representative ~~verbally and~~ ~~in writing~~ about:**(c) affirm on the SRE report that the ASC has complied with the patient notification requirements of 105 CMR 140.308(B)(1)(c)”* | **Make the following correction:**[140.308 (B)(1)(c)] *“(c) affirm on the SRE report that the hospital has complied with the patient notification requirements of 105 CMR 140.308(B)(1)()~~(c)~~****(b)****.”*  |  |
| **4** | 105 CMR § 140.308(C)(2)(c) | **Patient notification (30-day)**The proposed amendment to the provision on 7-day patient notification [140.308(B)(1)(b)] does not specify how ASCs should notify patients, leaving the option to provide oral notification alone. The absence of a written record raises concerns that some patients may not receive all of the information to which they are entitled in the initial aftermath of an SRE. It is possible to promote documentation and to introduce a measure of accountability through the 30-day letter. | **Create a separate subsection to address patient notification within 30 days** Amend the 30-day patient notification provision to require a reference to the initial 7-day communication as follows: [140.308 (C)(2)(c)] *(c) provide a copy of the updated SRE report to the Department, ~~the patient~~ and any responsible third-party payer.”****(d) Notify the patient or patient representative by:***1. ***A letter that summarizes the event, the ASC’s investigation, and its findings. This letter should reference the initial notification provided under 105 CMR § 140.308(B)(1)(b) including, at a minimum the date of the communication, how it was delivered, and a general statement of the information conveyed.***
2. ***The updated SRE report***
 | The proposed reference to the 7-day notification could be accomplished through a simple introductory sentence, for example, “As Dr. X explained to you on July 1, you experienced a [type of SRE] while in our care. “If this recommendation is not addressed in the regulation, we suggest that it be included in Departmental guidance.  |
| **5** | 105 CMR § 140.308 (C)(2)(b)(4) | **Timing of corrective actions** The proposed amendments—including expanding corrective actions to encompass those “developed, implemented and to be monitored”— to 140.308(C) “Preventability Determination” are welcome; however, as written, the provision appears to refer to only those corrective actions that have *already* been implemented. | **Reword corrective actions reporting obligation to encompass both actions already implemented as well as those planned.**[140.308(C)(2)(b)(4) *“description of* ***the*** *~~any~~ corrective* ***actions ~~developed,~~ that have or will be implemented and ~~to be~~ monitored*** *~~measures taken~~ by the ASC following discovery of the SRE;”*  |  |
| **6** | 105 CMR § 140.308 (D)(6) | **MassHealth reimbursement provision**The new MassHealth reimbursement provision under “Reimbursement for SREs” 140.308(D)(6) lacks clarity as drafted:***“(6) For services to MassHealth members, the ASC shall perform the documented review process and reporting pursuant to 105 CMR 140.308 (C) and (D) but is not subject to 105 CMR 140.308(D).”*** | **Revise the MassHealth provision so that it more clearly indicates the desired action.**  | We endorse what we take to be the underlying principle that a facility’s internal investigation into an SRE should not be influenced by reimbursement considerations.  |
| **SERIOUS INCIDENTS** |
| **7** | 105 CMR § 140.307(A),(C) | **7-day report for immediately reportable events**It is unclear whether incidents that are immediately reportable (and do not qualify as SREs) should also be reported by written report within 7 days in addition to making the immediate notification.We note that 140.307(C) requires that “any *other* serious incident…” (italics added) be reported within 7 days by written report, which could be interpreted to *not* include any incident reportable under 140.307(A & B).  | **Clarify whether immediately reportable incidents listed in 105 CMR §140.307(A, B) should *also* be reported in writing within 7 days.**  |  |
| **8** | 105 CMR § 140.307(D) | **Overlap with SREs/duplicate reporting** For events that meet the definition of both a Serious Incident and an SRE, the regulations are unclear as to whether or not facilities should submit two separate reports within seven days (one as a Serious Incident, the second as an SRE):*(D) If an ambulatory surgery center makes a report of any incident pursuant to 105 CMR 140.307(A), (B) or (C), and the incident meets the definition of Serious Reportable Event in 105 CMR 140.308(A), the ambulatory surgery center* ***also*** *shall comply with the requirements of 105 CMR 140.308.*It is our understanding that:* 1. Any event which qualifies both as an SRE under 105 CMR § 140.308 and as a Serious Incident under § 140.307(A or B) is reported immediately by phone to DPH and then submitted as an SRE in accordance with the requirements of § 140.308.
	2. Any event which qualifies both as an SRE under § 140.308 and as a Serious Incident under § 140.307(C) is reported solely as an SRE in accordance with the requirements of § 140.308.

However, the phrase “*the ambulatory surgery center* ***also*** *shall comply with the requirements of 105 CMR 140.308*” suggests that two reports should be filed – one as a Serious Incident and the other as an SRE. | **Clarify in Department guidance how ASCs should report events that qualify as both Serious Incidents and SREs.**The following is a suggested approach that we expect would clarify obligations, minimize duplicate reporting, and accomplish the state’s goals for event reporting:1. If an immediately reportable serious incident is also an SRE – immediate report + SRE protocol
2. If immediately reportable serious incident but not an SRE – immediate report + report in writing within 7 days as a serious incident
3. If not immediately reportable and not an SRE, report in writing within 7 days as a serious incident
 |  |
| **9** | 105 CMR § 140.307(C) | **Reference to SADEs under Serious Incidents**We support removing all references to SREs from the Serious Incident regulations (140.307) as proposed in the amended regulations; however, the proposed amendments also *add* a reference to SADEs that *does not apply to all clinics*. Serious Incidents (140.307(C)):*“A clinic shall report to the Department any other serious incident~~, or serious reportable event pursuant to 105 CMR 140.308(A) (SRE)~~ occurring on premises covered by the clinic’s license that seriously affects the health and safety of a patient(s) or that causes serious physical injury to a patient(s)* ***or a medication error that meets the definition of a Serious Adverse Drug Event (SADE) pursuant to 105 CMR 140.308(A)*** *within seven* ***calendar*** *days of the date of occurrence of the event.”*Given that new SADEs regulations:1. only apply to ASCs, not all clinics; and
2. already require reporting within 7 days,

we believe the reference to SADEs in 105 CMR § 140.307 (C) should be removed.  | **Remove the reference to SADEs in 140.307(C) “Serious Incidents”:**1. *Each clinic shall report to the Department any other serious incident~~,~~* ***or*** *accident ~~or serious reportable event pursuant to 105 CMR 140.308(A) (SRE)~~ occurring on premises covered by the clinic’s license that seriously affects the health and safety of a patient(s) or that causes serious physical injury to a patient(s) ~~or a medication error that meets the definition of a Serious Adverse Drug Event (SADE) pursuant to 105 CMR 140.308(A)~~ within seven* ***calendar*** *days of the date of occurrence of the event.*
 |  |
| **10** | 105 CMR § 140.307(B) | **Abuse & neglect definitions:** Currently, regulation 140.307(B) does not define the terms abuse, neglect, mistreatment, or misappropriation of patient [or resident] property.  | **Add definitions for *abuse, neglect, mistreatment, or misappropriation of patient [or resident] property* by applying definitions in** [**105 CMR §155.003**](http://www.mass.gov/eohhs/docs/dph/regs/105cmr155.pdf) **(long-term care facilities)** (Note, however, that these definitions utilize the defined terms “patient” and “resident” in 105 CMR §155.003.1 If this narrows the scope of the obligation, clarify the appropriate definition of “patient” and “resident.”) “Resident” is defined as “an individual who resides in a long term care facility licensed under M.G.L. c. 111, § 71,” and “patient” as “an individual who receives health, homemaker or hospice services at his or her residence from an individual employed by a home health agency, homemaker agency, or a hospice program.  |   |
| **SADEs** |
| **11** | 105 CMR § 140.308 (E) | **Overlap with SREs**SADEs reporting obligation overlaps with SREs, leaving it unclear whether hospitals should submit two separate reports (one as a SADE and a second as an SRE): ***(2) If a SADE also is an SRE, the hospital shall also comply with the requirements of 105 CMR 130.332(B), (C) and (D).*** | **Clarify in Department guidance how SADEs that also qualify as SREs should be reported, including whether or not ASCs should submit two separate reports.** |  |
| **12** | 105 CMR §140.308 (E)(3)  | **Reporting pharmacy-related SADEs** [140.308 (E)(3)]1. **Production, compounding and dispensing—**The statute [M.G.L. c.111 § 51H(b)] specifies that it applies to *dispensing*, in addition to producing and compounding. However, the proposed regulation omits “dispensing.”
2. **Off premises—**The regulation does not clearly state that provision (3) applies to SADEs that occur *off*-premises of an ASC. For example, a patient is treated at an ASC after consuming the wrong medication which was mistakenly dispensed by an outside pharmacy?
 | **Amend 140.308 (E)(3) to clarify that provision (3) of the SADEs regulations:**1. **Includes SADEs that result from the production, compounding, *and dispensing* of pharmaceuticals or drug preparation by a pharmacy**
2. **Applies exclusively to SADEs that originate off the premises of the reporting ASC**

Suggested language:**(3)  Upon first discovering, through diagnostic evaluation and assessment of an individual patient, that a SADE has resulted from a patient’s use, consumption or interaction with any pharmaceutical or drug preparation produced, compounded, or dispensed at a pharmacy not on the premises of the ASC, an ASC ~~a hospital~~ must report the event…** |  |
| **13** | 105 CMR § 140.308 (E)(3)  | **Reporting to MedWatch**Because dispensing-related SADEs are not reportable to the federal MedWatch program, 140.308 (E)(3) would be clearer if separated into two sentences: one that addresses reporting SADEs that occur off- premises to the originating pharmacy; and a second that addresses the reporting of SADEs to MedWatch. | **Separate out the federal MedWatch reporting requirement in 140.308 (E)(3) as its own sentence for clarity:** **(3)  …**~~a hospital~~ **an ASC must report the event to** ~~the federal MedWatch Program, as well as~~ **the pharmacy,** ~~was produced or compounded~~ **in addition to any** ~~all~~ **other reporting requirements. An ASC must also report to the federal MedWatch Program a SADE resulting from a pharmaceutical or drug preparation produced or compounded at a pharmacy not on the premises of the ASC.** |  |
| **14** | 105 CMR §140.308 (E) | **Error in reference to “hospitals” in clinic regulations.** The SADEs language in the clinics regulations mistakenly references hospitals instead of ASCs [140.308 (E)]: ***(1) Within seven days of the date of discovery of a medication error that occurs or occurred on the premises of the hospital and that meets the definition of a SADE, a hospital shall report the SADE to the Department as specified in guidelines of the Department.******(2) If a SADE also is an SRE, the hospital shall also comply with the requirements of 105 CMR 130.332(B), (C) and (D).******(3) Upon first discovering, through diagnostic evaluation and assessment of an individual patient, that a SADE has resulted from a patient’s use, consumption or interaction with any pharmaceutical or drug preparation, a hospital must report the event to the federal MedWatch Program, as well as the pharmacy from which the drug was produced or compounded in addition to all other reporting requirements.”*** | **Replace ‘hospital’ with ‘ASC’ throughout SADEs regulations for clinics and reference correct regulations for ASCs reporting SREs.** *(1) …premises of the* ***ASC*** *and that meets the definition of a SADE, a****n******ASC*** *shall report the SADE to the Department as specified in guidelines of the Department.**(2) If a SADE also is an SRE, the* ***ASC*** *shall also comply with the requirements of 105 CMR* ***140.308******~~130.332~~****(B), (C) and (D).**(3) Upon first discovering, through diagnostic evaluation and assessment of an individual patient, that a SADE has resulted from a patient’s use, consumption or interaction with any pharmaceutical or drug preparation, a****n******ASC*** *must report the event to the federal MedWatch Program, as well as the pharmacy from which the drug was produced or compounded in addition to all other reporting requirements.”* |  |