



Ligature Risk in Hospitals Listening Session

Moderated by Nicole Cooney
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Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® event. All lines will remain in a listen-only mode until the feedback session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect. I will now turn the call over to Nicole Cooney, thank you. You may begin.

Announcements & Introduction

Nicole Cooney: Good afternoon, everyone. I'm Nicole Cooney from the Provider Communications Group here at CMS, and I'll be your moderator today. I'd like to welcome you to this Medicare Learning Network Listening Session on Ligature Risk in Hospitals. CMS wants your feedback on draft guidance for Appendix A of the State Operations Manual and the Chapter 2 Certification Process addressing Ligature Risk in hospitals and psychiatric hospitals.

We want to provide direction and clarity around the care and safety of psychiatric patients at risk of harm to themselves or others. We are seeking your input on compliance with the Conditions of Participation and the Ligature Risk Extension Request process. Before we get started, you received a link to the presentation in your confirmation email. The presentation is available at the following URL go.cms.gov/npc; again, that URL is go.cms.gov/npc.

Today's event is not intended for the press, and the remarks are not considered on the record. If you are a member of the press, you may listen in, but please refrain from asking questions during the question and answer session. If you have inquiries, contact press@cms.hhs.gov. At this time, I'd like to turn the call over to Mary Ellen Palowitch from the CMS Quality, Safety, and Oversight Group. Mary Ellen?

Presentation

Mary Ellen Palowitch: Thank you, Nicole. Thank you for your interest in the Draft Ligature Risk Guidance for Hospitals and Psychiatric Hospitals. Let's get started with my brief presentation, so we have plenty of time for your comments and feedback.

Slide 2. Acronyms. A list of acronyms used in the written version of the presentation is listed as a resource for you.

Slide 3. Agenda. Today I'm going to walk through the draft revisions to the CMS State Operations Manual related to Ligature Risk. I want to thank the individuals and organizations who've already submitted comments and questions for our review. Later in this call, there will be opportunity for listeners to provide feedback which we will consider as we move to finalize the guidance. We are extending the deadline for comments since this call was scheduled after the prior deadline. Comments will be accepted until midnight on June 28th. Information regarding how to submit comments will be shared at the end of this session.

To get the presentation started, first, I'll give some background on the current Ligature Risk guidance as well as our plan to update it. We will be taking into account both internal and external comments and feedback. The draft revisions were released via the CMS QSO 19-12 Memorandum on April 19th. I'll briefly cover the contents of the memo.



Next, I'm going to review the draft revisions to Appendix A for hospitals. Although the memo lists draft chapter 2 revisions first, today I'm going to walk through the Appendix A revisions to the Conditions of Participation for Patient Rights and Physical Environment.

Then, I'll review the draft Ligature Risk Extension Request process for inclusion in Chapter 2 of the State Operations Manual. Finally, there will be time for your comments and feedback. I do not anticipate responding to questions today; however, as stated, your questions and comments will be considered as we move to finalize the guidance. I am unable to provide a timetable for a release of the finalized guidance at this time.

Background Information

Slide 5. Background. In December 2017, we released CMS QSO 18-06 memo addressing Ligature Risk. Our intention at that time, as stated in the memo, was to eventually revisit the guidance in order to clarify expectations and further update as needed to reflect current issues in hospitals. To provide some context for the need for the guidance, it came to our attention a few years back that Ligature Risks were primarily being identified as Physical Environment issues. Some hospitals were permitted to identify the Ligature Risks, develop mitigation strategies, but not repair or remove these risks. The Ligature Risks are also a concern for Patient Rights.

Medicare regulations require hospitals to provide care to patients in a safe setting. Patient Rights requirements cannot be waived. Some surveyors were not citing hospitals for noncompliance with Patient Rights requirements, but instead focusing on the Physical Environment requirements. To address this issue, CMS clarified that Ligature Risk are indeed a Patient Rights issue and maybe a Physical Environment issue as well.

The current and draft Ligature Risk guidance impacts first, hospitals with psychiatric units and locked psychiatric units in emergency departments. Second, psychiatric hospitals. And third, Critical Access Hospitals with distinct part psychiatric units. It is important to point out that Patient Rights and Physical Environment requirements apply in all hospital locations. Patients with behavioral health issues may receive care in all hospital settings, but the specific Ligature Risk requirements are limited to psych units and psych hospitals as mentioned.

The Ligature Risk extension process was first discussed in the December 2017 memo but wasn't memorialized in the State Operations Manual at that time. The draft guidance addresses processes for hospitals certified by state survey agencies or hospitals deemed by accrediting organizations for participation in Medicare.

QSO-19-12 Memorandum – Draft Ligature Risk Guidance

Slide 7. QSO-19-12 Memorandum. The memo attached to the draft Ligature Risk guidance was released by CMS on April 19th. The memo briefly explained our intent and asked for your feedback on the draft revisions. As mentioned earlier, comments were due June 17th, but with this presentation, we are extending the comment period to June 28th, a week from tomorrow. We encourage you to submit any questions or feedback if you haven't already.



SOM Appendix A Revisions: Patient Rights

Slide 9. Appendix A Patient Rights. The requirement to provide care in a safe setting applies in all hospital locations and is not limited to Ligature Risk issues. As you can see when reviewing Appendix, A, guidance is written to help surveyors assess compliance and to help hospitals better understand how to achieve compliance with Medicare requirements. The draft revisions to Patient Rights are intended to help with clarifications based on feedback and questions received since first released in late 2017.

I do not plan to explain the specifics of our draft revisions during this presentation. To date, we have received numerous comments from individuals, organizations, associations, and other interested stakeholders. We plan to continue our review in order to determine the optimal language to finalize the guidance. While, I will not discuss the comments received in great detail, we have identified the following recurrent scenes in the comments submitted so far and planned to address these issues as well as any other submitted by June 28th as part of our comprehensive review.

These items include application to patients at risk of harm to others, clarification regarding units where ligature-resistant requirements apply including emergency departments, locked versus unlocked units, expectations for other clinical units providing care to suicidal patients, impact in locked Geri psych or dementia care units, screening versus assessment, and when and where each may be required, identification of levels of risk, the use of video monitoring and one-to-one observation, identification and categories of risk items, environmental risk assessments, clarification regarding education and training of staff including what staff and how often they should receive training, and finally surveyor consistency. I look forward to hearing your comments and questions regarding Patient Rights during this call as well as receiving those submitted electronically.

SOM Appendix A Revisions: Physical Environment

Slide 11. Appendix A Physical Environment. Similar to Patient Rights, the requirements for the hospital physical plant and environment to be designed to ensure the safety and wellbeing of patients is not limited to Ligature Risk. Numerous other topics are also covered under this standard in Appendix A. If you're not familiar with the formatting of conditions in standards in Appendix A, you might find it confusing as was mentioned by some.

Today, however, I'm focusing on the draft Ligature Risk related content in the Physical Environment Condition of Participation. Some of the themes of comments received to date regarding Ligature Risk and Physical Environment include clarification of Patient Rights versus Physical Environment requirements, use of the term mitigation, impact in designated spaces such as nursing stations and other staff related areas, construction and facility guidelines, expectations regarding ligature-resistant equipment and hardware, the use of waivers. Finally, survey procedures, and where to cite deficiencies. Again, I look forward to hearing your Physical Environment and Ligature Risk comments shortly and reviewing those to be submitted electronically.

SOM Chapter 2: Ligature Risk Extension Requests

Slide 13. Chapter 2, Ligature Risk Extension process. Finally, I'd like to cover the draft new section in chapter 2 of the State Operations Manual detailing the Ligature Risk Extension Request process. Condition level, or substantial noncompliance with Medicare regulations places hospitals on 60-day termination track, potentially



threatening their participation in Medicare. We recognize, however, that many of the renovations required to come back into compliance with both Patient Rights and Physical Environment specific to Ligature Risk may take more than 60 days to complete.

We developed the Ligature Risk Extension Request process to give hospitals more time to come into compliance when the only outstanding condition-level issues are related to Ligature Risk. To date, the majority of hospitals are able to complete necessary actions within a few months or under a year. There are some hospitals, however, in need of longer periods of time, and we developed processes for ongoing review, monitoring, and renewal of these lengthy requests. The Ligature Risk Extension Request process was first addressed in the December 2017 memo.

The new section included in the QSO 19-12 memo released in April includes various processes based on whether your hospital is deemed to participate in Medicare or not as well as, whether the noncompliance was first identified by State survey agency or accrediting organization surveyors. The Ligature Risk Extension Request processes once finalized will be spelled out in chapter 2 of the State Operations Manual. Some of the comments received regarding the draft new section include request for clarification of processes for deemed and non-deemed hospitals.

The role of CMS Central Office and Regional Offices, State survey agencies, and accrediting organizations. Frequency for submission of hospital update, facility hardship to come into compliance, survey implications when Ligature Risk Extension Requests are approved and ongoing, and current survey and enforcement processes as compared to those related to the Ligature Risk Extension Request processes.

Ultimately, our goal is for hospitals to be in substantial compliance with Medicare regulations. We want our most vulnerable patients, including those at risk of harm to self, to be safe in our health care settings. I want to thank you for participating on this call. As a reminder, comments can be submitted until June 28th at midnight, not a minute after. The email address for submission of comments is included in the listening session materials. We encourage all to submit comments; however, we want to remind you that we have already received requests for clarification in the areas mentioned on the call today. Now, I'll turn the presentation back over to Nicole, thank you.

Feedback Session

Nicole Cooney: Thank you, Mary Ellen. Slide 15 outlines the logistics for today's listening session. CMS is seeking input on three topics. There will be an opportunity to get into the queue for each topic, so please limit your inputs to the topic that we announce. You'll have a maximum of 3 minutes to provide your input. When your line is open, please provide your name and organization. As a reminder, this event is being recorded and transcribed. We'll now hear your feedback on Topic 1 Patient Rights Requirements. All right, Dorothy, we're ready for our first caller.

Operator: To provide feedback, press star followed by the number 1 on your touchtone phone. To remove yourself from the queue, press the pound key. Remember to pick up your handset to assure clarity. Once your line is open, state your name and organization. Please note your line will remain open during the time you're providing your feedback, so anything you say, or any background noise will be heard in the conference. Please hold while we compile the roster. Please hold while we compile the roster.



As a reminder, if you would like to provide feedback, please press star followed by the number 1 on your touchtone phone.

And there's no feedback at this time.

Nicole Cooney: Okay, we'll move on to the next topic, Physical Environment Requirements. Dorothy we'll take the first caller.

Operator: To provide feedback, press star 1 followed by —, to provide feedback, press star followed by the number 1 on your touchtone phone, again that is star 1.

We have Heather Porter on line.

Heather Porter: Hi, good afternoon. Thank you for taking our comments. I'm Heather Porter. I'm the Chief Clinical Officer at Newton Medical Center, which is a 103-bed Acute Care Geri Psych Unit is the unit that these comments are in regards to. I would just ask that there be clarification regarding the objective requirements in relationship to ligature-resistant equipment, ligature-resistant furniture, and supplies on a Geri-Psych Unit as that is where in the state, we have had challenges with surveyor interpretation. And the dollar amount for correcting the milieu is substantial, and we want to ensure that we're correcting it with equipment and furnishings that are going to be compliant and not made to be changed when another surveyor comes out 30 days from there. Thank you.

Mary Ellen Palowitch: Thank you, Heather, for your feedback.

Operator: As a reminder, to provide feedback, press star followed by the number 1 on your touchtone phone. We have Peter Edis online.

Peter Edis: Hello, I'm with part of the Rockies Regional Medical Center in Salida, Colorado. I'm one of the Vice Presidents here. And my question --- it's actually a question, and that is how do these requirements apply to a Critical Access Hospital that does not have a distinct part unit or any type of psych services?

We do receive psychiatric admissions to our emergency room. We have local mental health come and assess them after they're medically cleared and then they are held until they are placed in an appropriate facility or otherwise discharged. So, the question is, how did the Ligature Risk requirements apply to an emergency department in our setting? Thank you.

Mary Ellen Palowitch: Peter, thank you for your question. I'll briefly answer that, but I think we'll provide more clarification later. The draft guidance that is out --- that was released via this memo ---is specific to hospitals with psych units and psychiatric hospitals and Critical Access Hospitals that have distinct part unit. The specific Ligature Risk requirements are not, at this time, applicable in Critical Access Hospitals.

However, I will remind you that the Conditions of Participation for Critical Access Hospitals, similar to the Conditions of Participation for hospitals- they are different, do expect care to be provided in a safe setting. So, if an issue came up on survey, you would be expected to demonstrate how you are providing care in a safe setting.



It may not be meeting the strict requirements that we have right now just because hospitals and Critical Access Hospitals have different Conditions of Participation. So, at this time, we want you to keep your patients safe, but the Ligature Risk Extension Process and the strict ligature-resistant requirements are not applicable in CAHs except in the dedicated psychiatric unit. Thank you for that question.

Operator: And there is no further feedback at this time.

Mary Ellen Palowitch: This is Mary Ellen again. I want to again - I want to add one more thing because this is important. Many hospitals and some but not all Critical Access Hospitals are deemed for participation in Medicare by accrediting organizations. Accrediting organizations are required to comply at a minimum with CMS requirements, but accrediting organizations can also have stricter requirements.

So, if you are a hospital or CAH that's deemed for participation in Medicare by an accrediting organization, they may have requirements that exceed ours, and you would be expected to meet those requirements. So, if you are deemed for participation in Medicare, I would strongly encourage you to be in touch with your accrediting organization to clarify those expectations. Thank you.

Operator: As a reminder, to provide feedback, press star followed by the number 1 on your touchtone phone, that is star 1.

One moment.

And we have Western Hospital on line.

Rebecca Vesely: Hi, this is Rebecca Vesely at a 160-bed inpatient psychiatric hospital. We had to close three of our units due to some Ligature Risk at our last Joint Commission survey, and one of the issues that I was wondering about was our facility is 165 years old. I've seen things on the Joint Commission website regarding the height from the floor, meaning that anything like even low to the floor is considered Ligature Risk but nobody has addressed the height of the ceiling. Some of our ceilings go from anywhere from 10 to 14 feet in these areas, and I didn't know if that would be --- if there is a ceiling height that we could allow or are we going to have to actually put in some solid ceilings in those rooms?

Mary Ellen Palowitch: Hi, this is Mary Ellen, and I don't have the answer to that question right now, but please also submit that question in writing. I know we received a similar question about ceilings. I don't know that I've heard anything about height, so I really appreciate you pointing that out. Thank you.

Operator: As a reminder, to provide feedback, press star followed by the number 1 on your touchtone phone, that is star 1.

One moment.

We have Tracey Colander on line.



Tracey Colander: Hi, good morning. My question is in follow up to the ceiling question, and that is about whether or not you have a requirement that speaks to whether or not you have to have a solid ceiling for specific populations that may not have the wherewithal to access a drop ceiling such as a dementia population?

Mary Ellen Palowitch: Thank you for that question and I don't have any answer to that at this time as I'm not an engineer. So, I don't have that information, but we do plan to address issues related to ceilings, and I know that has been a common theme of questions regarding the type of ceiling in corridors and in group therapy rooms and private rooms and on different types of units. So, thank you for bringing that to my attention today.

Operator: As a reminder, to provide feedback, press star followed by the number 1 on your touchtone phone, that is star 1.

And there is no further feedback at this time. I'll turn the call back over to you, Nicole.

Nicole Cooney: Okay, we will move on to topic 3, Ligature Risk Extension Request Process. Dorothy we'll take the first caller.

Operator: To provide feedback, press star followed by the number 1 on your touchtone phone, that is star 1.

And there's no feedback at this time. I'll turn the call back over to you, Nicole.

Nicole Cooney: Okay, I'll open up the line, does anyone have a comment on any of our three topics? And as a reminder, those three topics are Patient Rights Requirements, Physical Environment Requirements, or Ligature Risk Extension Request process. Any comments on one of those three topics, Dorothy, we can queue up.

Operator: As a reminder, to provide feedback, press star followed by the number 1 on your touchtone phone, that is star 1.

And there's no feedback at this time. I will turn the call back over to you, Nicole.

Additional Information

Nicole Cooney: Okay. Since we have taken all of your comments, we will go ahead and end the session for today. You may email your feedback to the addresses listed on slide 16, and audio recording and transcripts will be available in about two weeks at go.cms.gov/npc. Again, my name is Nicole Cooney, and I'd like to thank our presenter and also thank you for participating in today's Medicare Learning Network Listening Session on Ligature Risk in Hospitals. Have a great day, everyone.

Operator: Thank you for participating in today's conference call. You may now disconnect. Presenters, please hold.