PATTON HEALTHCARE CONSULTING, INC.

Accreditation | Compliance | Patient Safety

*News from The Joint Commission and CMS*

The Patton Post | September 2020

## Inside This Issue:



Welcome back if you had some vacation time away from the office this summer, we are optimistic it was a pleasant respite for you. We hope you enjoyed seeing our vacation photos as much as we enjoyed seeing yours from our photo contest!

September is usually a month of refocusing on accreditation preparation, but this pandemic year with restaurants and schools closed, some hospitals still in crisis mode, and states widely varied in their degree of opening, seems very different. We will discuss CMS' plans to resume surveys later in this issue–but it basically means that if you were due and your state is open again for business, you have a greater chance of a survey taking place than we have seen since February.

This pandemic year has also possibly resulted in changes within your organization with colleagues retiring or taking on new roles. At Patton, this has been true as some consultant colleagues and friends have used this time to reconsider their work/life balance; we wish them a long and healthy retirement.


We at Patton want to thank each and every one of you – clients we have worked with for years, colleagues and friends, and our own. The level of expertise you all have brought to the industry is unparalleled while undoubtably saving lives of staff, patients, and their families. While we will miss you, we hope you thoroughly enjoy your retirement!

We also want to welcome all those that have taken on new roles! We have enjoyed meeting and working with those who have taken on new roles since this pandemic began. We want to welcome our newest PHC team member, Missi Halvorsen, RN, MSN. Missi brings more than 35 years of extensive healthcare industry experience serving as Director of Corporate Compliance, Director of Nursing, and extensive consultative roles; fitting in seamlessly with our team. This fun and clever photo is of Missi and a colleague on her most recent remote survey. Please join us in welcoming her!

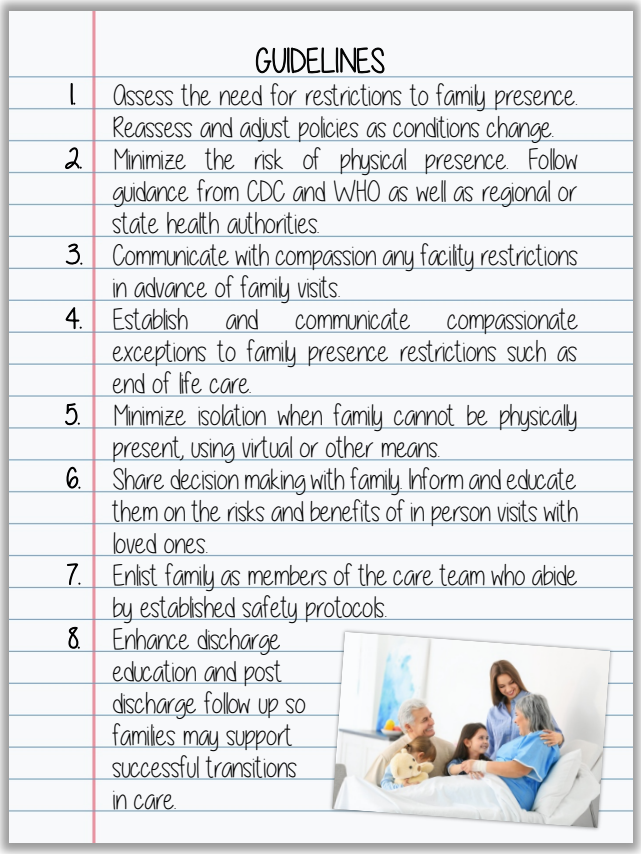
# *Perspectives*

**Family Visitations:**

The pandemic cut off many families from the opportunity to visit with loved ones while hospitalized or in a nursing home. The lead article in *Perspectives* is about Joint Commission's endorsement of the Planetree International Coalition's *Person-Centered Guidelines for Preserving Family Presence in Challenging Times*.

These guidelines developed by patients, families, healthcare leadership, and clinicians are intended to help the provision of compassionate care and family contact. They developed eight guidelines to help promote this contact.

Since both TJC and CMS are resuming surveys, only when their respective criteria are met by the pandemic in your state and/or county, we can envision visitation rights becoming a topic of discussion. In particular, if your state is open for business and infection trends are steadily decreasing, if you have not resumed visitation rights, this could be a focus of attention. In addition, when surveyors are looking at patient education documentation it seems likely they would look to see documentation of the participation and education of family members in anticipation of discharge.




**Clinical Respiratory Services:**

*Perspectives* has an article describing a "loosening" of the eligibility requirements for inclusion of clinical respiratory services in the home care program. Previously, an agency had to serve ten patients in a year to qualify for accreditation of the service, but now that threshold is being lowered to one patient. Reduced eligibility requirements can be advantageous to some organizations, whereas others might view this as a new mandatory and costly survey eligibility tailoring rule. In the article, TJC did provide a link to a second document that helps to explain what meets and what does not meet this new expanded service definition.

https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/clinical_resp_flyer_3_09pdf.pdf?db=web&hash=7A4E7010E1001ED1B93CBE610448484A

***Consistent Interpretation*:**

This month's column discusses PI.01.01.01, EP 4, which requires hospitals to collect data on significant discrepancies between preoperative and postoperative diagnoses. TJC indicates that last year only 0.78% of organizations were scored deficient on this EP. They also discuss EP 5 which requires the collection of data on adverse events related to moderate or deep sedation. Again, the percentage of organizations scored deficient is low at 0.64%. These infrequent findings may in reality be somewhat higher as we see gaps more often in our preparatory surveys. There is often a huge book of PI data and the total amount of information appears overwhelming at times, limiting time to identify gaps in completion of requirements. The Joint Commission's PI expectations always include two tracks: the mandatory PI expectations described in

the standards plus the organizations identified priorities chosen from their high risk and problem prone processes.

Do take a look at the *Consistent Interpretation* column for the suggestions TJC provides on examples of some issues which should be (1) reported and (2) analyzed for these two elements of performance. We wish to emphasize that there are two critical functions, one being data collection and the second, perhaps more importantly, data analysis, because we have seen multiple media stories in the past year about data being collected, but a failure to identify adverse trends in the analysis phase. The essential and difficult part of the PI process is identification of potential adverse trends so that you can analyze possible causation and seek to improve the results.

To grow awareness of the Joint Commission's mandatory PI requirements, we created a self-assessment PI readiness tool listing of all the elements of performance where TJC has identified a specific data element that must be collected and analyzed. Please find the tool attached to the newsletter email; should you wish to have the editable version, please email us at ExpertAdvice@PattonHC.com.

**Update on USP:**

TJC posted an update on the status of USP chapters 797 and 800 to one of its blogs. The blog can be accessed at: https://www.jointcommission.org/resources/news-and-multimedia/blogs/dateline-tjc/2020/08/20/update-on-medication-compounding-compliance/. Similar content was posted to the August 26th edition of *Joint Commission Online*.

As you probably already know, USP Chapter 797 is undergoing additional analysis due to appeals and the planned implementation date has long passed with no new date yet announced. USP Chapter 800 is referenced and only enforceable under USP Chapter 797 v 2019 (unofficial at this time), thus USP Chapter 800 is advisory only for now.

In their blog, TJC mentions that some organizations may have already undertaken renovations to become compliant with USP Chapter 797 v 2019. The good news is that for the most part any changes you made to become compliant with the 2019 version should be compliant with the older 2008 version with one exception. This exception is for segregated compounding areas (SCAs) which are basically a room with an ISO class 5 PEC, or primary engineering control, but no secondary engineering controls or special HEPA filtration of room air.

In the 2019 version of USP 797, the SCA can be used to compound what are called Category 1 sterile products. These have only 12-hour (room temperature) or 24-hour (refrigerated) beyond use dates due to conditions under which they were made. Category 2 sterile products are made in a primary engineering control (PEC), surrounded by a secondary engineering control, and can have longer expiration dating.

In the 2008 version of USP Chapter 797, categories of sterile products were not based on the conditions under which they are made, but rather the complexity of the compounding process. In the 2008 version of USP Chapter 797, only what were called "low risk" sterile compounds could be made in an

SCA. A low risk sterile compound was defined as 3 or fewer sterile components being manipulated into the final product. Medium risk sterile compounds could not be prepared in an SCA per USP Chapter 797, v 2008.

During the COVID-19 national emergency, however, USP issued interim guidance to organizations allowing medium risk compounding in an SCA with up to 12-hour dating at room temperature or 24 hours under refrigeration. This exemption is anticipated to end when the national emergency ends. Here is the link to the USP resources, see the May 18 update specifically: https://go.usp.org/Compounding_EC_Resources

The TJC blog also discusses USP Chapter 800, which some organizations may have chosen to implement already. If you have implemented USP Chapter 800, TJC states they will evaluate "portions" of it. TJC suggested some portions which would be applicable, but we have refrained from duplicating that content here, because it was stated as "not limited to." To better understand this issue about what is applicable we suggest reviewing the USP guidance on this subject available at: https://www.usp.org/sites/default/files/usp/document/our-work/compounding/compendial-applicability-of-usp-800.pdf

The USP guidance is fairly clear that the administration portion of USP chapter 800 is not compendially enforceable as it is not associated with compounding as described in Chapter 797 or 795. We were unsure exactly what TJC was saying in their blog and on *Joint Commission Online*, so we asked. TJC confirmed they will not be evaluating the safeguards called for in Section 14 of the USP Chapter 800 on the administration of hazardous medication, except in those situations where the requirements were adopted by hospital policy.

We would encourage our readers to take a look at the multiple "Must" requirements in that section and the one "Should" recommendation. The "Must" requirements include things such as wearing protective PPE, using closed system transfer devices for antineoplastics when the dosage form allows, and handling used gowns worn during administration as trace hazardous waste. These all appear to be reasonable safeguards to help protect staff administering hazardous medication. In addition, the guidance from USP Chapter 800 is directionally consistent with OSHA and NIOSH expectations for employee safety when handling hazardous medications or substances.

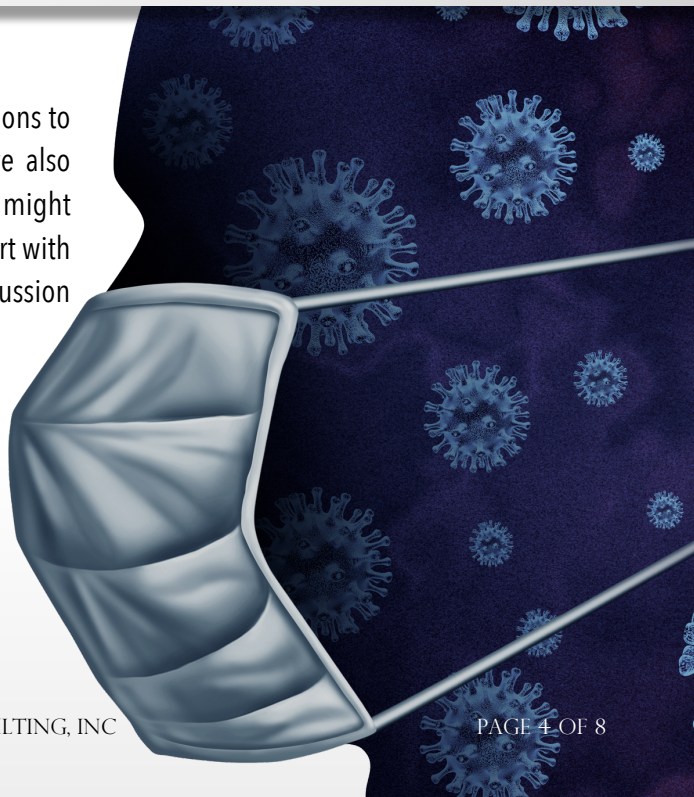
If this was not complex enough already, there is another enforcement agency to consider and that is your state boards of pharmacy. State regulations may be more stringent and your organization would be expected to be compliant with those more stringent requirements. In addition, if state regulations are more stringent, TJC would survey to the more stringent expectations.

**Survey Process Modifications:**

We had heard at the TJC Consultants Forum that there would be modifications to the survey process now that surveys were somewhat resuming. We have also received some feedback from clients who have undergone survey and as you might imagine, COVID-19 is quite a focus of discussion. We have seen surveys start with a combined leadership, infection control, and emergency management discussion focused on covid.

The good news is, most of the questions seem general in nature and, somewhat like surveyors, are orienting themselves to how difficult things were rather than looking for flaws. The types of questions asked included:

- What waivers did you use?
- What education had to be provided to staff?
- What services did you adjust or modify?



- What changes had to be made relative to housekeeping?
- What was done for screening of patients and employees?
- What issues arose relative to PPE and how did you manage?
- What changes were made relative to security?
- What changes were made to your IC plan as a result of your learning?
- What did you learn?
- What would you do differently if you had to do it over again?
- What issues were identified relative to the EM plan for communications, security, utilities, staff support, patient support, and supplies?
- Did you do any reprocessing of PPE?
- Did you establish alternate care sites?
- Did you accept volunteer practitioners and go through credentialing and privileging?
- Did you encounter air pressure relationship or filtration challenges?
- Did you implement any extra support for staff?

On a more general note, we are also hearing that other routine group sessions were a combination of "in room" and remote activities with some participants joining via Zoom or Microsoft Teams. For patient tracers, two screen mirroring or large screen LCDs were used to promote social distancing.

# EC News

**Minneapolis EM Response:**


The lead article this month is about Hennepin County Medical Center in Minneapolis and their emergency management response to COVID-19, coupled with a response to the civil unrest in their city after the death of George Floyd. It presents an interesting challenge that many organizations may not have considered in developing new inputs or scenarios to emergency medical planning. But unfortunately, this is a scenario that seems to occur more often in our society that may warrant consideration by more organizations.

They discuss some of the challenges posed by the unrest, such as the city shutting down public transportation which many hospital staff needed to get to work. The hospital opened up additional free parking for staff and set up socially distant cots and food for those who did not want to commute. To some extent, they noted that staffing needs were reduced as patients did not want to venture to the hospital during the unrest.

There is also a boxed insert of additional references from the CDC on riot control agents, ASPR TRACIE specifically providing insights from Minneapolis, and the National Highway Safety Administration providing guidance for Fire and EMS personnel. The one from ASPR TRACIE describing activities in Minneapolis seemed most pertinent. This is definitely worth sharing with your emergency management planning team and a consideration for a future drill.

## Reopening Closed Sites:


EC News has had several articles in recent months about reopening sites that have closed and this month there is another insightful article on this subject. They discuss the potential loss of sterile products damaged by humidity if air conditioning was shut down and those products were not removed prior to the shutdown.

They also advise about piped medical gas systems, which if shut down and not maintained, must be reinspected by an American Society of Safety Engineers inspector per ASSE 6020 before restarting patient care. There is also a boxed insert providing links to resources from TJC, CDC, CMS, EPA, and ASHE on the subject of reopening.

In particular we would like to suggest downloading the ASHE material. The link to their covid resources is: https://www.ashe.org/COVID19resources

Hopefully normalcy will be returning and reopening occurring, so now is a good time to evaluate this guidance for a safe reopening.

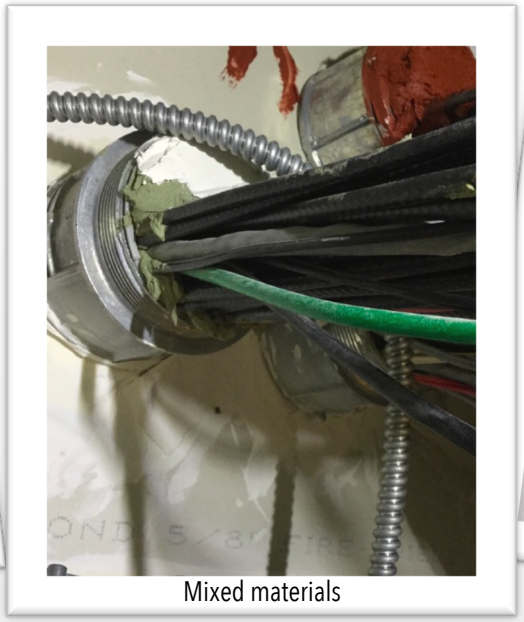
## Rated Walls:

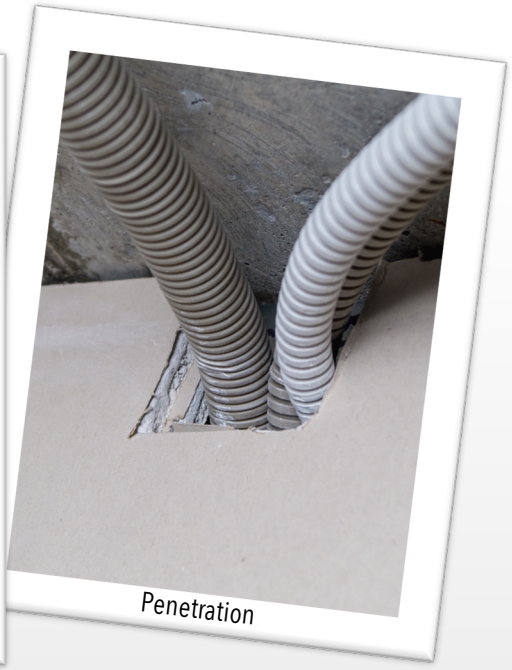
EC News has an article on Rated Walls, and while this sounds like a rather dry or mundane subject, it is a great primer for administrative or quality staff who are not life safety code specialists themselves. There are also some tips and photographs in the article that may be new information, even for those in facilities leadership.

The authors warn that drywall compound is not a listed firestop material for sealing openings in the wall. They also highlight the defect of using what is called a "scab patch" or a piece of drywall placed on top of a hole and on top of the existing sheet rock. The patch must be cut out and the new sheet rock sealed into the wall, not just screwed on top of the existing wall. They display photographs of how to properly do this type of repair.

Lastly, they warn about mixing fire stop materials in the same penetration. If you are using a new product, the old firestop material in need of repair should be removed and the entire patch sealed with your new product. Again, there are photographs displaying the flawed technique, which based on our observations, is more common than you would like to think.


Scab patch


Mixed materials


Penetration

# CMS

**Resuming Surveys:**

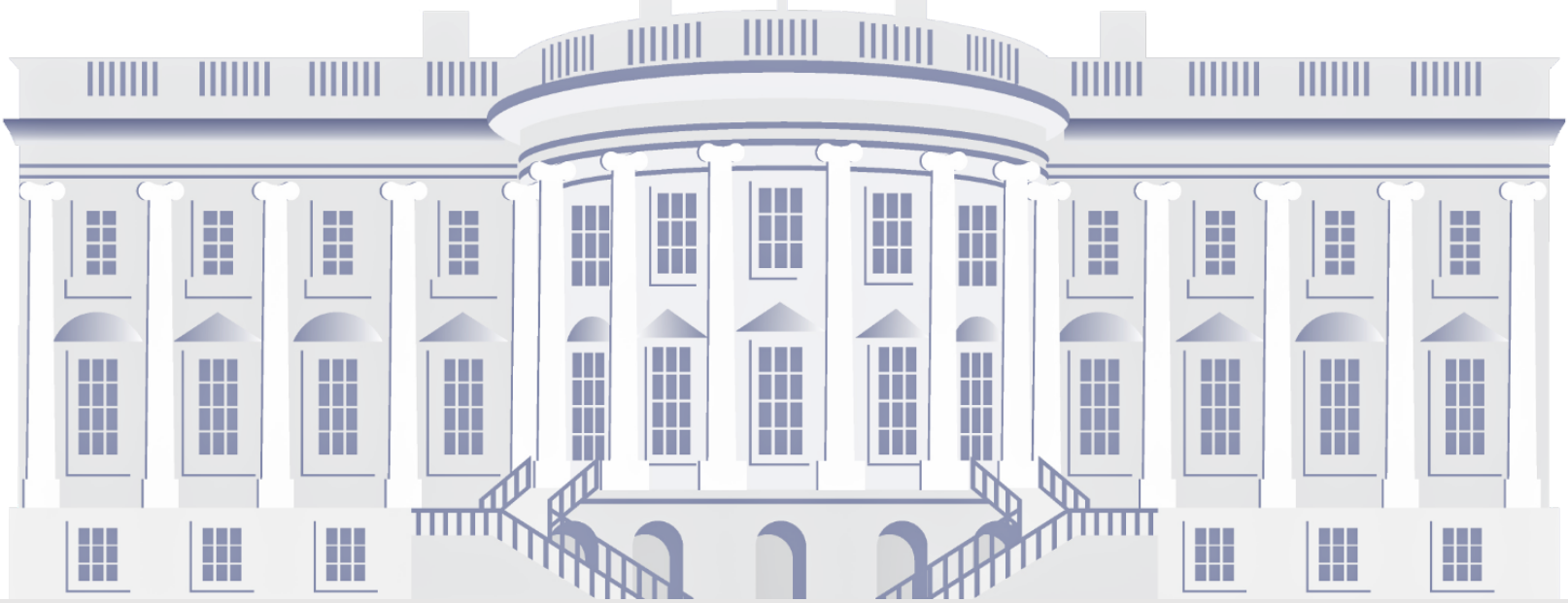
CMS was busy this month, issuing several QSO memos and a new emergency COP. QSO-20-35, issued August 17 described the process by which CMS will resume survey activities. The memo has guidance for the long-term care industry, the "non-long-term care industry," and laboratories. Hospitals would come under the non-long-term care guidance. CMS is somewhat resuming survey activities for hospital, ls in locations that meet Phase 3 White House Guidance for reopening. CMS provides a link in the memo to that White House Guidance and we have duplicated that link here: https://www.whitehouse.gov/openingamerica/


Basically, the White House gating criteria to begin reopening requires a downward trend in influenza-like symptoms for two weeks and a downward trend in confirmed COVID-19 cases for two weeks, or a downward trend in percentage of positive Covid testing for two weeks and hospitals treating all patients without crisis care, and a robust testing program for healthcare workers. These same gating criteria must be met three successive times, so basically you are talking about improved trends for six weeks.

CMS will now be expanding non-long-term care survey activities to include:

- Revisit surveys for past noncompliance that cannot qualify for a desk review
- Complaint surveys that are less than immediate jeopardy, or higher that have not yet been completed
- Initial surveys of new providers
- Special purpose renal dialysis facilities (a temporary location like a summer camp or emergency location, see CFR.494.120)
- Past due recertification surveys with a statutorily required survey interval
- Past due recertification surveys without a statutorily required survey interval.

The memo also describes that prior enforcement cases that had been suspended will now be completed, and some follow up activities may become "desk reviews" with documentation of corrective actions taken. This may include some IJ situations providing the IJ was removed and confirmed by survey.



**New COP:**

CMS also issued a 198-page Federal Register announcement about new rules for nursing homes and laboratories and a new COP for hospitals. CMS simultaneously issued a press release on this same subject (which is nice because it is much more concise than the 198-page document) and they issued two QSO memos to the nursing home industry explaining the new requirements in detail.

A similar QSO memo applicable to the hospital industry has yet to be released but be alert for it arriving soon. We know the basics of what it will say from the Federal Register announcement which are that laboratories will have to report the results of COVID-19 testing and hospitals will have to report data on the utilization and availability of beds for COVID-19 patients and the availability of selected equipment such as PPE and ventilators.

We could not get the link posted in the Federal Register about the data elements to work, however we have seen it posted since by the AHA and Becker's Newsletters. The data elements are available at: https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf. The requirement for hospitals to report data will be at a COP level.

On August 26, CMS issued two additional QSO memos, QSO-20-37 discussed required reporting of COVID-19 test results for CLIA certified laboratories and QSO-20-38 discusses new infection control requirements as well as mandatory testing of staff and residents in nursing homes. The second memo includes an attachment which is an updated version of the CMS COVID-19 Focused Survey Tool.

This tool includes recommended observation techniques for the CMS surveyor to assess compliance with infection control practices for COVID-19. We would encourage all readers to download the tool and consider the techniques being used by CMS surveyors to observe staff and patient practices. The QSO 20-38 memo can be downloaded from:
https://www.cms.gov/files/document/qso-20-38-nh.pdf

## CONSULTANT CORNER

Dear Readers,

Thanks to all who participated in our giveaway contest!! Every single photo we received was either picturesque or comical and we really enjoyed seeing them all!

Upon random selection, we are pleased to announce the winning photo!! This stunning image was taken by Kathryn T. from New York. Who else wouldn't mind a view like this?! Here is a little sneak-peek of some Patton gear heading to NY.

Wishing continued health and wellness to each and every one of you!

Thank you,

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