CMO REPORT

FROM THE DESK OF
Amy Tucker, MD, MHCM, Chief Medical Officer, Upstate University Hospital
Associate Dean for Clinical Affairs, College of Medicine

UPSTATE UNIVERSITY HOSPITAL

June 26, 2024

Thank You, Karen!

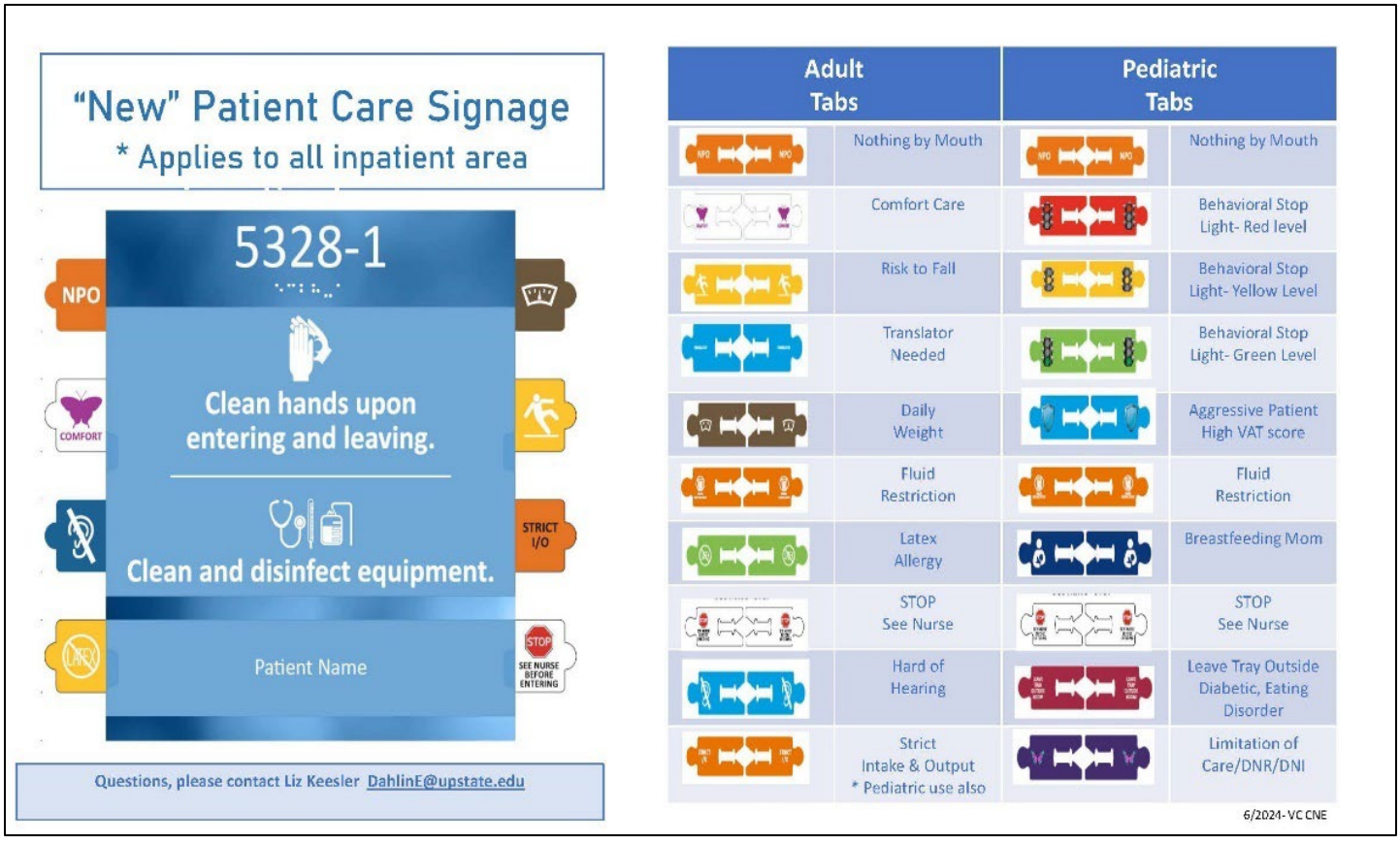
By Dr. Matthew Glidden

Special thanks to Karen Wentworth, MPH, MSW, RRT, CPXP for her years of support as the Director of Patient Experience and more recently, the Interim Patient Experience Officer. Karen has decided to transition back to the bedside in support of our understaffed Respiratory Therapy Department. Upstate and the patients we serve have benefitted greatly from the work Karen has done in these roles. We wish her the best of luck.

Patient Experience will be incorporated within the Quality Department as we move forward and with the guidance of Vizient, will be restructured to promote and assist in shaping and improving the patient experience at Upstate.
During this time of transition and restructuring, all patient experience related issues and issues regarding patient behavioral agreements can be directed to Bethany Sciotti, the Director of Patient Relations who can be reached at 315-464-5597 or via email at sciottib@upstate.edu.

New Patient Care Signage

By Elizabeth Keesler



ALERT — IMMEDIATE ACTION REQUIRED
ADVISORY — PRIORITY BUT NOT FOR IMMEDIATE ACTION
UPDATE — FOR INFORMATION; UNLIKELY TO REQUIRE ACTION

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New Patient Care Signage is being implemented hospital wide at Upstate University Hospital, Upstate Community Hospital, and Upstate Golisano Children's Hospital. This new patient care signage will help to improve communication and reduce medical risks for patients, visitors, and healthcare professionals. These standardized signs will also help create uniformity between units and across the organization. Please contact Elizabeth Keesler at 315-464-9227 for questions.

New Chemical Restraints Order Set Available

By Julie Briggs and Joseph Burczynski

A new order set named Adult and Peds Acute Care Chemical and Non-Chemical Restraints IP and ED is available when medications are used as a restraint. This will replace the Restraints – Acute Care Panel that is currently used. This is for patients who require restraints to protect against injury to themselves or others who are not in an inpatient psychiatric unit. **Please reference the attached document for further information.**

Hospitals Must Get Written Patient Consent for Pelvic Exams

On April 1, 2024, the U.S. Department of Health and Human Services released Revisions and Clarifications to Hospital Interpretive Guidelines for Informed Consent (attached), specifically as it relates to patients undergoing sensitive examinations such as pelvis and prostate exams, especially if the patients will be under anesthesia. **Please take a moment to review these updated guidelines.** For questions or concerns, please contact QSOG_Hospital@cms.hhs.gov.

Reminder: Pulsara Go-Live for Trauma and Burn Teams

By Dr. Christopher Tanski

Effective Thursday, June 20th, Upstate University Hospital's Trauma and Burn teams began utilizing the Pulsara communication platform for team activations. Our EMS partners also switched from using radio communications to Pulsara to communicate with hospitals.

Upstate University Hospital's STEMI and Stroke teams have been using the Pulsara application to improve team communication for several years now and both teams have noticed significant improvements. Additionally, the CNY region adopted Pulsara for use by EMS providers earlier this year and our Emergency Departments are now receiving pre-notification of ambulance arrivals via the Pulsara application.

We are excited about the benefits of using this system and hope to bring more of our teams onboard in the coming months. Any questions can be directed to Dr. Christopher Tanski at tanskic@upstate.edu.

Best Practice Advisory (BPA) for Ordering Advanced Imaging Removed

By Jennifer Carey

In September 2021, as the result of a mandate from the Centers of Medicare and Medicaid Services (CMS), we implemented Appropriate Use Criteria (AUC) when ordering advanced imaging exams (CT, MRI, Nuclear) through the vendor CareSelect. This system scores the appropriateness of the advanced imaging study through use of a BPA and that information is placed on claims.

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On January 1, 2024, CMS rescinded the mandate for Appropriate Use Criteria (AUC) on advanced imaging exams. Charges reflecting the AUC information was removed as they are no longer needed. **Starting July 1, 2024, providers placing advanced imaging orders will no longer see this BPA.**

Pharmacy Shortage and Backorder Updates

By Greg Meola

Recent pharmaceutical supply chain disruptions have increased national drug shortages dramatically, which can compromise or delay medical treatment and increase the overall risk of medication errors. Raw material shortages, manufacturing and quality problems, transportation delays and low profit margin product discontinuations have become routine.

The Chief Medical Officer and Upstate Pharmacy leadership are seeking to keep our Upstate clinicians informed about the most critical drug shortages affecting our organization and offer substitutions whenever possible. **Please see information below.** We will provide updates as they are available.

Drug	Current Status	Possible Product Alternative Recommendations/Contingency Planning
CURRENT BACKORDERS		
Diazepam injection	Current Inventory: ~230 vials Next shipment: Unknown	Alternative messaging placed in EPIC for providers to urge utilization of oral options or IV midazolam if injectable therapy is necessary. Pharmacists educated in dose equivalency for IV midazolam,
Penicillin intramuscular injection (BICILLIN-LA)	37 syringes	All doses being reserved for patients with syphilis. All other indications require ID input prior to dispensation.
Dextrose 50% emergency syringe	Current Inventory: Zero	Pharmacy IV Lab is batching refrigerated syringes of D50 – no immediate impact on patient care
BCG Vials	Current Inventory: 57 vials	Open line of communication between Cancer Center Pharmacy/Urology as planning is fluid – no immediate impact on patient care.
RESOLVING/RESOLVED BACKORDERS		
Ciprofloxacin for injection		
Ketamine injection		
Liothyronine for injection		

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Lorazepam for injection		Alternative rule in EPIC no longer appears, can return to normal usage.
Acyclovir for injection		Alternative rule in EPIC no longer appears, can return to normal usage.

New York State Department of Health Advisory

Please take a moment to read the attached New York State Department of Health Advisory regarding Legionellosis.

Clinical Documentation Improvement (CDI) Tip for June 2024

By the CDI Physician Advisory Group

Importance of Discharge Summaries: The Discharge Summary is the final diagnostic summary and statement of hospitalization, used as a communication tool between discharging hospital and community-based providers. It should include any treated conditions, necessary pending work up, and continued communication items to ensure patients transition from hospital to home in a safe and effective manner, reducing risk of readmissions. **Please see this month's CDI Tip (attached).** For questions or additional information, please email the CDI Team at CDI@upstate.edu.

Exceptional Teacher Recipient for June 2024

By Dr. Lawrence Chin

Sherrie LaFrance-Hale, PhD, an assistant professor of Cell and Developmental Biology at the Norton College of Medicine at Upstate Medical University, is the June 2024 recipient of the Exceptional Moments in Teaching recognition.

The Norton College of Medicine recognizes exceptional teachers with the monthly "Exceptional Moments in Teaching" program. Honorees are selected via student assessments from courses and clerkships. Recognized teachers – including medical faculty, residents, nurses and other educators – are those who challenge students and provide an exceptional learning experience.

Comments from Dr. LaFrance-Hale's students:

"Dr. LaFrance-Hale for the second time (first in Cardiovascular System, then in Respiratory System) went above and beyond organizing review sessions for students to learn gross anatomy. Recognizing teaching assistants are crucial to student success, but not available due to enjoying their pre-residency lives, Dr. LaFrance-Hale stepped up to help us when we needed it. Her explanations are always clear, kind, and repeated when asked. She empathizes with our struggle as medical students. "

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"She is great. Cares about her students and makes sure we have the resources we need to Succeed. When the fourth year wasn't there for review, she sacrificed her own time to go over everything with us and recorded many informative videos that were relevant to the tested content. Does not feel like any of her material is a waste of time. Didn't mind going back and explaining. Explanations are very good."

"She is an amazing teacher; definitely one of the best professors here at Upstate. Dr. LaFrance-Hale is an amazing teacher and human being. She constantly makes me feel heard and is able to easily explain anything I am having trouble with. We love Dr. LaFrance-Hale!!"

Welcome New Clinicians!

Please join me in offering a warm welcome to the following new clinicians at Upstate Medical University:

ANESTHESIOLOGY
Michael Bamerick, CRNA
Paul Crescenzi, CRNA
Rebecca Fleckenstein, CRNA

MEDICINE
Jennifer Chiu, NP
Marija Kalas-Lukic, NP
Sarah Vartabedian, NP
Carolyn Walker, NP

PEDIATRICS
Darcie Morgan, NP

PSYCHIATRY
Tori Martin, NP
Edele Nozius – Louigarde, NP

RADIOLOGY
Ian Wilson, MD

SURGERY
Sydney German, NP
Oscar Manrique Mogollon, MD

Outstanding Physician Comments

Comments from grateful patients receiving care on the units and clinics at Upstate:

Adult Hematology Oncology Downtown: **Dr. Seung Shin Hahn** – wonderful! I believe between **Dr. Seung Shin Hahn** and **Dr. Bernard Poiesz** my life was saved. **Dr. Bernard Poiesz** – wonderful, kind, patient while working with my challenging health.

Breast Care Center: **Dr. Daniel Thomas** – friendly, compassionate, answered my questions, and was very helpful in discussing my issue.

Breast Care at CC POB: **Dr. Jayne Charlamb** was very friendly and explained my risks and things I could do to mitigate them well.

ED at Community Hospital: **Dr. Miriam Bernstein** took my situation serious and saw me for a follow up just a couple of days later in her office. I was prepared for surgery shortly after. **Dr. Vincent Calleo** – great! **Dr. Risa Farber** was amazing! She was very reassuring and detailed. **Dr. Joseph Heath** was kind, competent, interesting and was truly listening to everything I said. He took into account my concerns and prescribed effective medication. **Dr. Gary Johnson** was very kind, funny, and put me at ease. **Dr. James Mangano** – great! **Dr. Erin Underriner** fully explained everything.

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Family Medicine: **Dr. Kaushal Nanavati** was very inclusive with me regarding my care and overall health! He is a talented active listener and made me feel very comfortable and allowed very generous time with me!! **Dr. Kaushal Nanavati** is incredibly knowledgeable, talented, kind, helpful, and promotes optimal wellness and improved health as well as goal setting! I have been seeing **Dr. Clyde Satterly** for a couple of decades and have great respect for his insight and recommendations. **Dr. Clyde Satterly** has a calm and reassuring tone.

Family Medicine at Community: **Dr. Bushra Atta ur Rehman** – amazing doctor who listened and is focused on helping people. **Dr. Paula Brooks** took the time to make sure I understood my care going forward.

GEM: **Dr. Erin Underriner** was very compassionate when talking to me. She was unhurried and easy to talk to. I appreciated her follow up call the day after I was discharged.

GYNONC MI: **Dr. W Douglas Bunn** – amazing! **Dr. W Douglas Bunn** always makes the visit comforting and reassures me that everything looks good with tests, etc. I am so thankful and blessed I have the best gynecological oncologist in Upstate. I always recommend **Dr. W Douglas Bunn** to anyone I know experiencing issues of this nature. His knowledge and expertise saved my life.

Heart and Vascular Center: **Dr. Jamal Ahmed** – very professional and pleasant. Answered all my questions. **Dr. Kiran Devaraj** was wonderful! **Dr. Anthony Feghali** is an excellent doctor.

HEMONC CC: **Dr. Bhaskara Madhira** is excellent. He always takes the time to explain my options and makes sure to see if I have any questions. **Dr. Bhaskara Madhira** is always caring for his patients.

Inclusive Health Services: **Dr. Angana Mahapatra** always puts me at ease. Sometimes I walk in just really upset about a medical issue and walk out feeling like I have knowledge to empower me to handle whatever is going on and it's not the end of the world because sometimes it may feel that way when you are hit with a certain diagnosis. She is where she belongs which is caring for people, especially people struggling with HIV.

Joslin Center for Diabetes: **Dr. Runa Achyara** is a good listener. She is very approachable and answers questions with terms a layperson can understand. **Dr. Barbara Feuerstein** is a very caring person and an excellent physician. **Dr. Nisha Patel** was very thorough and all around wonderful. I appreciate how she took the time to explain everything to me. **Dr. Nisha Patel** also made sure my daughter understood what was happening, what they were looking for, and what to expect during the exam. One our way out she said, "I wish **Dr. Nisha Patel** could be my primary care doctor; I really liked her!" **Dr. Jason Sloane** always provides good ideas in my treatment and is always there to listen. **Dr. Jason Sloane** is the best. He listens, talks to you, and shows that he cares a lot about you. **Dr. Jason Sloane** is the most amazing doctor I've ever had the pleasure of working with. He's helped me improve my health dramatically and I know he has the best intentions when it comes to my continued health journey. **Dr. Jason Sloane** is always patient with you, takes his time, and explains everything that you ask about. He remembers you from visit to visit and truly cares about his patients!! My, all-time, favorite doctor.

Multidisciplinary Programs Cancer Center: **Dr. Mashaal Dhir** – very impressed by his demeanor and explanations. **Dr. Mashaal Dhir** was excellent. I felt like I was in very good hands. **Dr. Kristina Go** spelled out everything for us and listened and answered all our questions and we felt great knowing we were not rushed. I felt a partnership with **Dr. Lisa Lai** when

reviewing my case and treatment options. She listened to my concerns, respected what I said, and was very professional and compassionate. I appreciated feeling seen and heard throughout the appointment. **Dr. Jason Wallen** was very informative and allowed me to make decisions about treatment with care and guidance. **Dr. Jason Wallen** explained my issues clearly. He informed me of all procedures I may face, the good and the bad. Very personable and great 'bedside' manner. I feel good about what he says is the plan of treatment. I am confident with him as my doctor.

ONC OSW: **Dr. Rahul Seth** is excellent.

Peds Neph, Rheum, Integrative Med: **Dr. Dongmei Huang** was able to explain everything about my daughter's imaging as well as some very rare things to look out for in the future regarding her blood pressure and reproductive system. Although highly unlikely and very rare, it was good to keep those things in mind for my child's future health assessments. **Dr. Caitlin Sgarlat-Deluca** is so sweet and really cares about the patient and the family. I would 100% recommend her to anyone.

Pulmonology Clinic: **Dr. Phillip Gary** was so great! Informative and gave me his full attention. **Dr. Dana Savici** continues to provide excellent care to me. I have been very pleased with the care I have received from **Dr. Dana Savici**. She is thorough while still being conservative in not doing unnecessary or high-risk testing.

Regional Perinatal Center: **Dr. Robert Silverman** was fantastic and very kind.

Surgery – UH: **Dr. Anthony Feghali** was very friendly, and he explained my condition completely.

Surgery – UH LL022: **Dr. Kristina Go** and her team are wonderful, caring, very understanding, explained things very well, cared about my concerns, and answered my questions very well. I would, will, and do recommend this group to anyone.

Surgical Subspecialties at CC: **Dr. Lauren Rabach** really understood the reason why I needed the surgery. **Dr. Timothy Shope** – great doctor! **Dr. MacKenzie Trovato** was amazing, professional, friendly, and explained everything wonderfully. Highly recommend.

UHCC – Neurology: **Dr. Anuradha Duleep** – knowledgeable, concerned, and compassionate. **Dr. Anuradha Duleep** – caring and knowledgeable. **Dr. Sherif Elwan** really listened to me and is patient with me when I can't find my words. He really cares how I feel. **Dr. Kimberly Laxton** was excellent. She made me feel I was important, and she was focused to help me. She was extremely knowledgeable and had a very good way to explain things. **Dr. Corey McGraw** was great as usual! It has been such a pleasure to have **Dr. Corey McGraw** as my healthcare provider. He always takes his time explaining things and makes me feel like he actually cares about my health. 10/10 – would recommend him to others! **Dr. Luis Mejico** and his Residents were very thorough at listening to my concerns and explaining the situation in a way I could understand. I have never had a medical experience with a specialist that was as positive as my experience with **Dr. Luis Mejico** and his Residents. The Ophthalmic Resident and **Dr. Luis Mejico** were both very personable and knowledgeable and made me feel at ease. **Dr. Victoria Titoff** is amazing. It's clear how much she cares not just about the epilepsy but in all areas of my life. She was so validating when I told her about my struggles and the difficult decisions I had to make. I was feeling extremely anxious, borderline panicky, and I felt so much better when I left. Her support and encouragement were so helpful. I cannot say enough good things about her. **Dr. Victoria Titoff** was great, really listened

to everything I had to say, very empathetic, validating, and supportive. I never felt rushed. I have already recommended her to others.

University Cardiology: **Dr. Srikanth Yandrapalli** was clear, understanding, and compassionate. I was lucky to have him assigned to me for my heart cath at Upstate.

University Center for Vision Care: **Dr. Preethi Ganapathy** has a high degree of professionalism in addition to her kindness that, in my opinion, should be commended. She genuinely cares that I am fully informed during each visit. If I have questions, **Dr. Preethi Ganapathy** provides me with complete details, so I have a clear understanding. **Dr. Stephen Merriam** is excellent with my daughter who happens to have special needs. **Dr. Stephen Merriam** is very patient and does not rush!! **Dr. Stephen Merriam** was great, thorough, asked my 11-year-old questions, made us both aware of where her vision problems were at, and what our next steps were. The ease in which **Dr. Stephen Merriam** explained his concerns and opinions was excellent. I felt heard, I felt like all my questions and concerns were validated by him. The ease in how he spoke and made me feel about our situation was such a relief. He was very compassionate, but also very supportive and easy-going. **Dr. Robert Swan** and I exchanged pleasant conversation about a recently deceased physician who referred me to him. It was that kind of personal touch that brings quality to patient-doctor relationship.

University Geriatricians: **Dr. Andrea Berg** and all the staff were exceptional. We have already recommended your practice to friends and family. Thank you!

University Internists: **Dr. Tingyin Chee** is superb in every way. **Dr. Vincent Frechette** – simply the best. **Dr. Vincent Frechette** is always very thorough, explains things clearly, and is compassionate. **Dr. Vincent Frechette** is consistently great at diagnosis and treatment recommendations and is very personable. **Dr. Vincent Frechette** – pleasant and informative. **Dr. George Gluz** is such a good doctor. **Dr. Matthew Hess** has been great. He listens and makes helpful suggestions. I never feel rushed when seeing him. **Dr. Danielle Kochen** is consummately professional yet engaging in conversation…a very nice person. I would recommend **Dr. Sarah Lappin** any day. She is wonderful.

Univ Pediatric & Adolescent Center: **Dr. Joshua Bonville** were fantastic.

Upstate Brain & Spine Center: **Dr. Harish Babu** has excellent bedside manner. He is sweet, kind, and very pleasant. **Dr. Harish Babu** – wonderful, spent time with me, answered all of my questions, was very pleasant and knowledgeable. I am very happy that **Dr. Luis Mejico** referred me here.

Wound Care Center: **Dr. Monica Morgan** was very kind and informative.

3West at Community Hospital: **Dr. Sumera Ahmed** – very caring, listened well, and very competent.

4West at Community Hospital: Kudos to **Dr. Jivan Lamichhane**! Thanks for everything.

06B: **Dr. Danielle Kochen** was a fantastic doctor – caring, took time also for my needs. I'm very grateful.

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6th Floor at Community Hospital: **Dr. Timothy Damron**, my surgeon, visited me twice during my hospital stay. He was patient and welcomed any questions I had. I appreciated that. **Dr. Mark Emerick** was wonderful. He took the time to talk, explain, and listen. **Dr. Robert Sherman** – he's the best!

07A: **Dr. Richard Tallarico** and his team were very attentive and kept me informed on my medical condition and post-op recovery status.

Amy

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CDI Tip of the Month – Importance of the Discharge Summary

The Discharge Summary is:

Considered the final diagnostic statement for the entire hospitalization

A communication tool for hospital to community transition used to promote continuity of high-quality patient care and outcomes

The first document hospital coders review when they start coding any given hospitalization

The first document Recovery Auditors review to deny any hospitalization or remove diagnoses

Documentation Golden Rules for the Discharge Summary

Include a complete list of confirmed, possible, likely, and probable diagnoses identified during hospitalization

Ensure diagnoses acknowledged through query are included in the Discharge Summary

Ensure there is no conflicting documentation between what is contained in the Discharge Summary and what has previously been documented in the rest of the medical record

Ensure the Discharge Summary does not introduce new information that is not otherwise present in the medical record

Memory of significant patient information and diagnoses naturally diminish over time. Best practice is to ensure the Discharge Summary is written on the day of discharge.

May 2023

e-mail: cdi@upstate.edu
phone: 315-247-6920

ED Physicians and Clinicians

Order Set for Chemical Restraints

Adult and Peds Acute Care Chemical and Non-Chemical Restraints IP and ED

TRAINING CENTER OF EXCELLENCE
UPSTATE MEDICAL UNIVERSITY

EPIC SYSTEM UPDATE

Overview of Feature / Changes

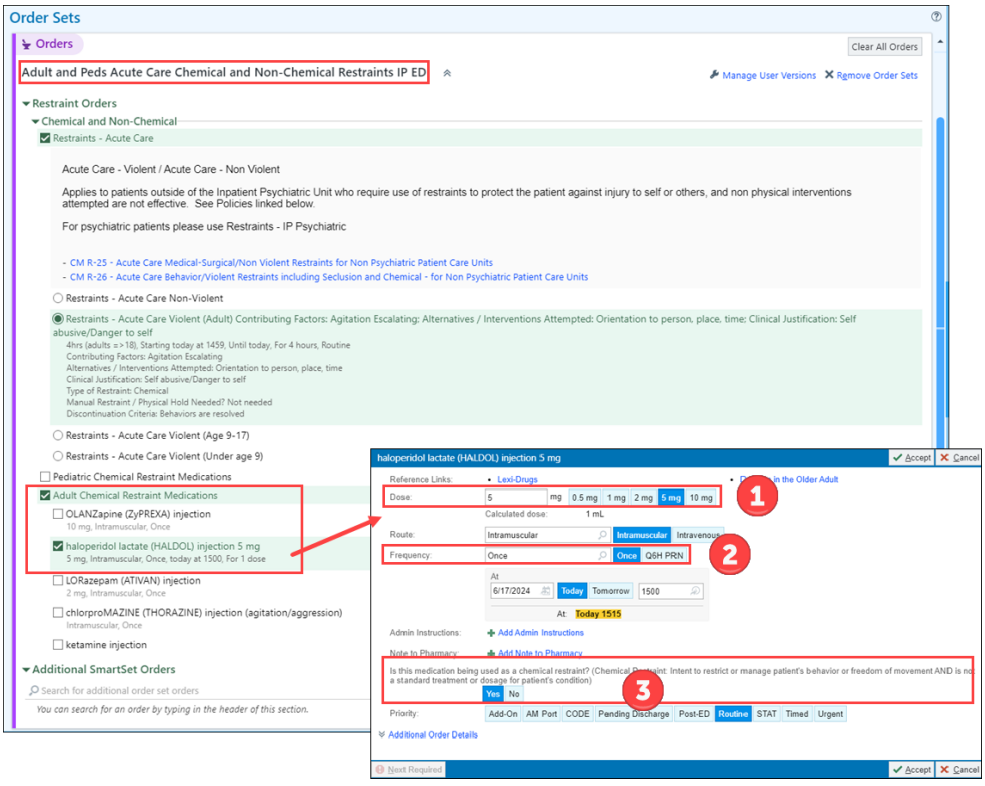
Effective June 18, 2024: A new order set named **Adult and Peds Acute Care Chemical and Non-Chemical Restraints IP and ED** is available when medications are used as a **restraint**. This replaces the **Restraints – Acute Care** panel currently used. This is for patients who require restraints to protect against injury to themselves or others who are not in an inpatient psychiatric unit. **The ED can use this new order set or the updated ED order set that includes the chemical restraint medications**.

New Order Set

A new *medications section* is included in the order set:

- **Peds Medications Affected:** Parenteral forms of lorazepam, haloperidol, olanzapine, ziprasidone, chlorpromazine, hydroxyzine, diphenhydramine.
- **Adult Medications Affected:** Parenteral forms of lorazepam, haloperidol, olanzapine, chlorpromazine, ketamine.

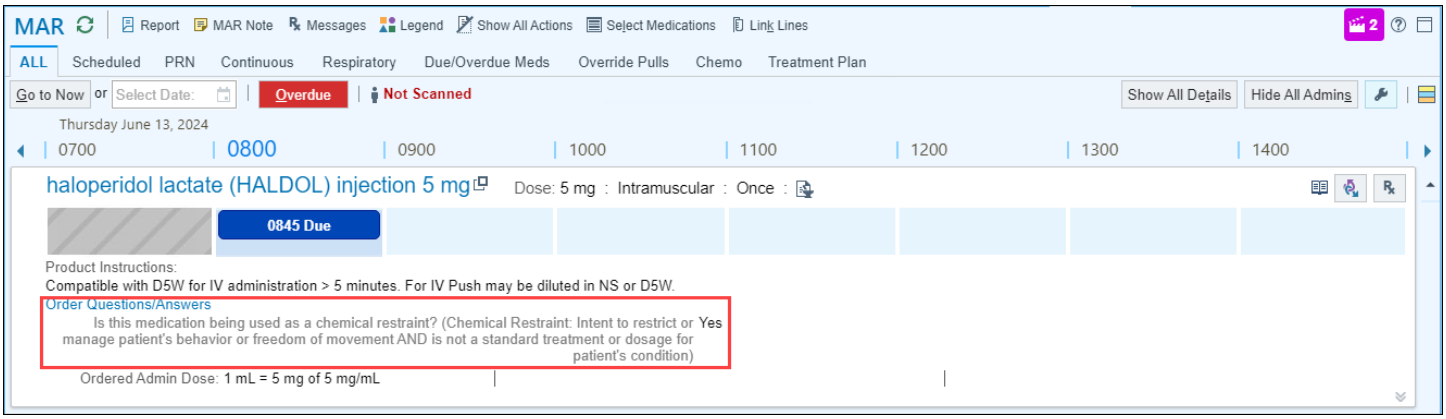
1. After selecting the medication, click it to see the details and **review the dose**.
2. The details section defaults to a *frequency of* **Once**.
3. A new question displays and defaults to **Yes** indicating the medication is being ordered as a chemical restraint. *This should not be changed to* ***No*** *within the order set.*



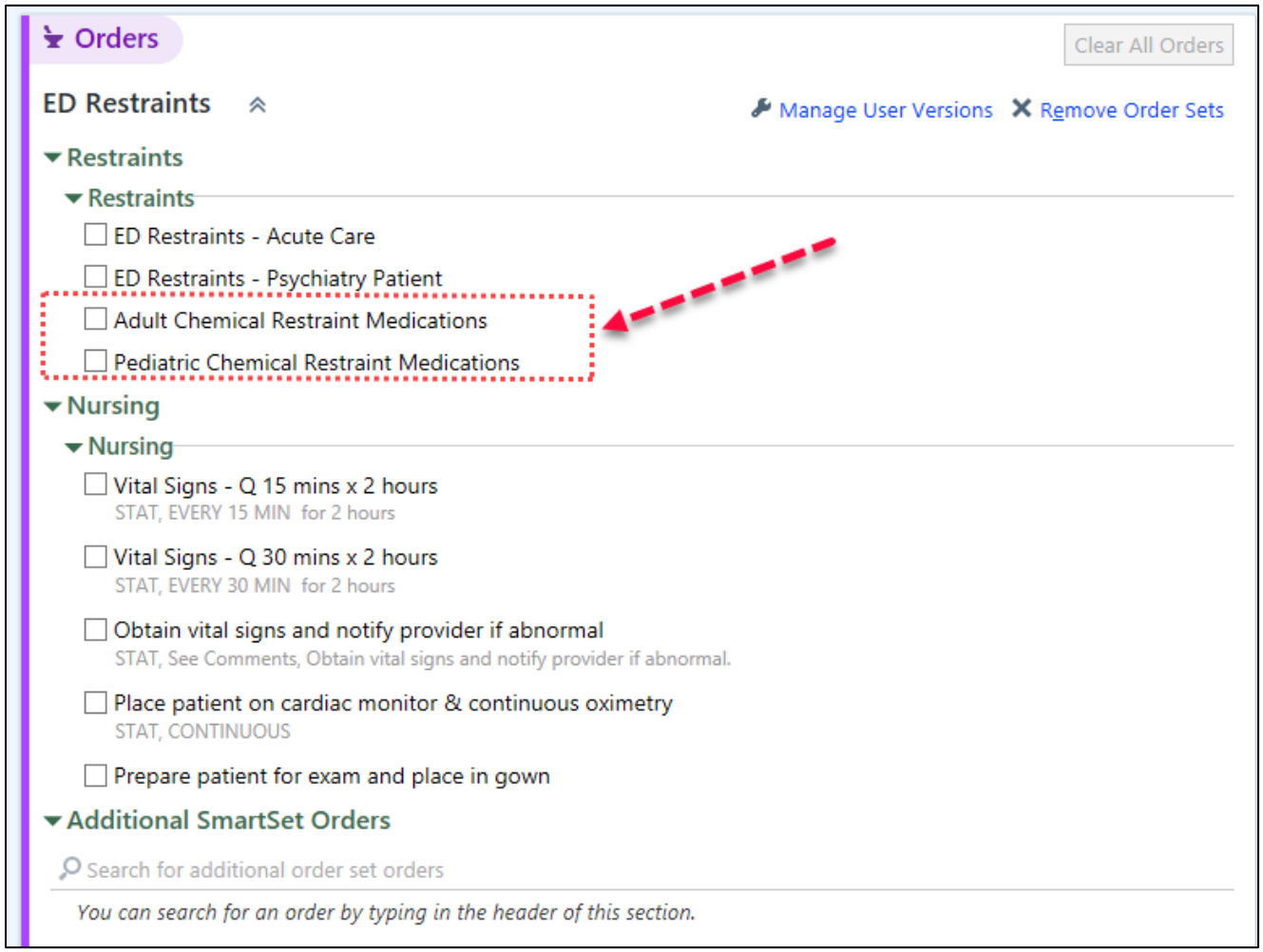
Important Note: If you order a medication outside of this order set, the question regarding whether it is being used as a chemical restraint ***must be answered as either Yes or No.***

Additional Information

Nursing will see a message on the MAR indicating this medication is being ordered for use as a chemical restraint.



Updated ED Order Set



UPSTATE
MEDICAL UNIVERSITY
ALAN AND MARLENE NORTON
COLLEGE OF MEDICINE

FACULTY EXCEPTIONAL MOMENTS IN **TEACHING**

Sherrie LaFrance-Hale, PhD, an assistant professor of Cell and Developmental Biology at the Norton College of Medicine at Upstate Medical University, is the **June 2024** recipient of the **Exceptional Moments in Teaching recognition.**

COMMENTS FROM LAFRANCE-HALE'S STUDENTS:

"Dr. LaFrance-Hale for the second time (first in Cardiovascular System, then in Respiratory System) went above and beyond organizing review sessions for students to learn gross anatomy. Recognizing teaching assistants are crucial to student success, but not available due to enjoying their pre-residency lives, Dr. LaFrance-Hale stepped up to help us when we needed it. Her explanations are always clear, kind, and repeated when asked. She empathizes with our struggle as medical students."

"She is great. Cares about her students and makes sure we have the resources we need to Succeed. When the fourth-year wasn't there for review, she sacrificed her own time to go over everything with us and recorded many informative videos that were relevant to the tested content. Does not feel like any of her material is a waste of time. Didn't mind going back and explaining. Explanations are very good."

"She is an amazing teacher; definitely one of the best professors here at Upstate. Dr. LaFrance-Hale is an amazing teacher and human being. She constantly makes me feel heard and is able to easily explain anything I am having trouble with. We love Dr. LaFrance-Hale!!"

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NEW YORK STATE OF OPPORTUNITY. Department of Health

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Executive Deputy Commissioner

NYC Health

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Ashwin Vasan, MD, PhD
Commissioner

DATE: 06/20/2024

TO: Healthcare Providers, Healthcare Facilities, Clinical Laboratories, and Local Health Departments (LHDs)

FROM: New York State Department of Health (NYSDOH)
New York City Department of Health and Mental Hygiene (NYC Health Department)

HEALTH ADVISORY: LEGIONELLOSIS

For All Clinical Staff in Internal Medicine, Pulmonary and Intensive Care Medicine, Geriatrics, Primary Care, Infectious Diseases, Emergency Medicine, Family Medicine, Laboratory Medicine, and Infection Control/Epidemiology

SUMMARY

- New York State (NYS) has a high burden of legionellosis. Clinical suspicion for the possibility of Legionnaires' disease, Pontiac fever, or extrapulmonary legionellosis coupled with culture of respiratory secretions is critical to the identification of and intervention in community clusters.
- Legionellosis occurs year-round, with increased incidence during the summer and early fall.
- Legionnaires' disease cannot be distinguished from other causes of pneumonia on clinical or radiologic grounds and requires diagnostic testing in hospitalized or at-risk patients with suspected pneumonia. **Clinicians should test for *Legionella* by respiratory culture, PCR, and urine antigen, especially if testing for other respiratory infections has been negative.** A single serology is not appropriate for the diagnosis of acute legionellosis. Please refer to the following diagnostic testing table for additional information.
- **Culture of the organism from respiratory secretions or tissues is the gold standard for Legionnaires' disease diagnosis and is the only way to identify and link clinical case(s) to a potential environmental source.** You must specifically request a culture for *Legionella* because this testing requires specialized media.
- **Confirmed *Legionella* isolates from any clinical specimen[1] should be submitted to the NYS Department of Health (DOH) Wadsworth Center Laboratories or the New York City (NYC) Public Health Laboratory (PHL) for serogrouping and whole genome sequencing (WGS)**.
- Report legionellosis cases promptly to the local health department (LHD)[2] where the patient resides. Cases in NYC residents should be reported to the NYC Health Department by calling the Provider Access Line at 866.692.3641.
    - If you are unable to reach the LHD, contact the NYSDOH BCDC at 518.473.4439 or by email at epiLegionella@health.ny.gov during business hours or 866.881.2809 evenings, weekends, and holidays.

[1] https://www.wadsworth.org/sites/default/files/WebDoc/CDRG%20NYState%202020_101920%202.pdf
[2] https://www.health.ny.gov/contact/contact_information/

Epidemiology

From 2019-2023, there were 4,359 legionellosis cases reported statewide. In 2021, NYS reported more cases of legionellosis than any other state.[3] In 2023, 18 community-acquired and 23 facility-related clusters or outbreaks were investigated in NYS, including NYC. The statewide incidence rate was 4.1 cases per 100,000 population, with the highest burden in residents of counties located in Western and Central New York. The national case-fatality rate is estimated to be 10% for community-acquired and 25% for healthcare-acquired Legionnaires' disease.[4]

Information for Healthcare Providers, Facilities, and Clinical Laboratories

Clinical suspicion of Legionnaires' disease should be elevated for such persons presenting with pneumonia especially if they report recent travel, recent inpatient care at a healthcare facility, recent exposure to hot tubs, or if the patient lives in a congregate setting such as a nursing home.

Testing for Legionnaires' disease guides clinical treatment and assists LHDs and NYS with detecting outbreaks and linking cases to potential environmental sources. Testing is critical for persons at higher risk for Legionnaires' disease, including persons aged 50 years or older; current or former smokers; persons with chronic lung disease, immunocompromising conditions, systemic malignancy, or comorbid conditions such as diabetes or renal/hepatic failure.

Respiratory tract specimens for *Legionella* culture should ideally be obtained before initiation of antibiotics, although antibiotics should not be delayed in order to obtain a specimen. Cultures can be ordered after the initiation of antibiotics.

Empiric treatment of community-acquired pneumonia in hospitalized patients should include adequate coverage for *Legionella* with either a macrolide (e.g., azithromycin) or a respiratory fluoroquinolone (e.g., levofloxacin). The CDC provides detailed information on clinical guidance and treatment regimens for Legionella infections.[5]

Pontiac fever is a less severe illness than Legionnaires' disease. Symptoms include fever and muscle aches; however, Pontiac fever does not present with pneumonia. Symptoms can begin within a few hours to 3 days after exposure to the bacteria, usually lasts less than a week, and patients typically do not require treatment.

Extrapulmonary legionellosis, although rare, has been identified as the cause of clinical infections as diverse as endocarditis, wound infections, joint infections, and graft infections, among others. A diagnosis of extrapulmonary legionellosis is made when there is clinical evidence of disease and diagnostic testing indicates evidence of *Legionella* at an extrapulmonary site.

Additional information, including detailed clinical guidance for *Legionella* infections, is available at the Centers for Disease and Control and Prevention's Resource Site.[6]

[3] https://wonder.cdc.gov/nndss/static/2021/annual/2021-table2i.html
[4] https://www.cdc.gov/investigate-legionella/php/healthcare-resources/testing-collecting-specimens.html?CDC_AAref_Val=https://www.cdc.gov/legionella/health-depts/healthcare-resources/cases-outbreaks.html
[5] https://www.cdc.gov/legionella/hcp/clinical-guidance/index.html
[6] https://www.cdc.gov/legionella/index.html

Diagnostic Testing

Test	Specimen Type	Advantages	Challenges
Culture (gold standard)	• Lower respiratory secretions (sputum) • Tissue	• Provides confirmatory lab evidence of Legionnaires' disease. • Detects ALL species and serogroups. • WGS can be conducted. • Comparison of clinical and environmental isolates to identify potential source.	• Clinicians must specifically request the specimen be cultured for Legionella (not a general respiratory bacterial culture) as specialized media (buffered charcoal yeast extract {BCYE} agar) is required. to ensure culture viability (e.g., pure colony isolates streaked on sealed BYCE agar plates or slants incubated for no more than 14 days and sent with cold packs or ice, but not frozen).
Polymerase chain reaction (PCR)	• Lower respiratory secretions (sputum) • Tissue	• Provides confirmatory lab evidence of Legionnaires' disease. • Detects *L. pneumophila* serogroup 1 as well as other species and serogroups.	• Must be reflexed to culture to perform WGS for comparison to environmental isolates to identify potential source of infection in outbreaks.
Urine antigen testing (UAT)	• Urine	• Provides confirmatory lab evidence of Legionnaires' disease. • ONLY reliably detects *L. pneumophila* serogroup 1.	• Cannot identify or rule out infection with other *Legionella* species/ serogroups. • Cannot be used for WGS. • Cannot be used to identify potential environmental source of infection in outbreaks.
Serology	• Blood	• Can diagnose acute Legionnaires' disease infection retrospectively.	• A single antibody titer is NOT diagnostic for legionellosis. • Requires collection of second specimen, 3–4 weeks apart, to detect a fourfold rise in antibody titer to a level >1:128. • Cannot be used to identify potential environmental source of infection in outbreaks.

Public Health Reporting

- Report cases promptly to the LHD[2] where the patient resides[7]. Cases residing in NYC should be reported to the NYC Health Department by calling the Provider Access Line at 866.692.3641 during business hours or 212.764.7667 evenings, weekends, and holidays.
- If you are unable to reach the LHD for cases residing outside of NYC, contact the NYSDOH Bureau of Communicable Disease Control (BCDC) at 518.473.4439 during business hours or 866.881.2809 evenings, weekends, and holidays.
- Laboratories should send all *Legionella* isolates to the appropriate PHL for serotyping and WGS as outlined in the NYS Laboratory Reporting of Communicable Diseases[1].
  - Cases in residents outside of NYC: isolates should be sent to the NYS Wadsworth Center Bacteriology Laboratory.[8]
  - Cases in residents of NYC: isolates should be sent to the NYC PHL using PHL eOrder. Select *Legionella* serotyping and send isolates to 455 1st Avenue, New York, NY 10016.

Questions regarding clinical or epidemiological information should be directed to your LHD or the NYSDOH BCDC at 518.473.4439 or epiLegionella@health.ny.gov. For questions pertaining to NYC residents, call the NYC Health Department Provider Access Line at 866.692.3641.

[7] https://www.health.ny.gov/professionals/diseases/reporting/communicable/
[8] https://www.wadsworth.org/programs/id/bacteriology/submission-guidelines

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-24-10-Hospitals

DATE: **April 1, 2024**

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revisions and clarifications to Hospital Interpretive Guidelines for Informed Consent

Memorandum Summary

- Based on **increasing concerns about the absence of informed patient consent** prior to allowing practitioners or supervised medical, advanced practice provider, or other applicable students **to perform training- and education-related examinations outside the medically necessary procedure** (such as breast, pelvic, prostate, and rectal examinations), particularly on anesthetized patients, we are reinforcing hospitals' informed consent obligations.
- **Requirements related to informed consent for hospitals are found throughout the Hospital Conditions of Participation (CoPs)**: the Patient's Rights CoP at 42 CFR 482.13(b)(2); the Medical Record Services CoP at 482.24(c)(4)(v); and the Surgical Services CoP at 482.51(b)(2).
- **Surveyors must ensure** that a hospital's patient informed consent policy and process, as well as its informed consent forms, contain elements and information that allow for a patient, or his or her representative, **to make fully informed decisions about their care.**
- **CMS is revising its hospital interpretive guidance about informed consent** in the State Operations Manual, Appendix A-Hospitals, to address this.

Background

According to a recent article on the *Annals of Surgery Open* website, "A growing number of states have statutes regulating the performance of sensitive examinations on anesthetized patients. The scope of the examinations covered includes breast, pelvic, prostate, and rectal examinations, increasing the impact of these laws on surgeons. There is a broadening focus on obtaining consent for any provider and learner performing these examinations."[1] This focus on the role of patient informed consent to obtain patient permission to perform these examinations

[1] *Annals of Surgery Open* 3(1):p e120, March 2022. | *DOI:* 10.1097/AS9.0000000000000120

has prompted CMS to reinforce the Hospital CoPs to revise our interpretive guidance regarding informed consent, and to clarify our expectations for hospitals regarding this issue.

The requirements related to informed consent for hospitals are found in the Patient's Rights Condition of Participation (CoP) at 42 CFR 482.13(b)(2); the Medical Record Services CoP at 482.24(c)(4)(v); and the Surgical Services CoP at 482.51(b)(2) and are further described in the State Operations Manual (SOM), Appendix A.

Informed Decisions

The right to make informed decisions regarding care presumes that the patient or the patient's representative has been provided information about his/her health status, diagnosis, and prognosis. Furthermore, it includes the patient's or the patient's representative's participation in the development of his/her plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or the patient's representative can understand, to ensure that the patient or the patient's representative can effectively exercise the right to make informed decisions. Hospitals must establish processes to ensure that each patient or the patient's representative is given information on the patient's health status, diagnosis, and prognosis. Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care. Hospitals must utilize an informed consent process that ensures patients, or their representatives, are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. See Appendix A, SOM at tag A-0131 for more information.

The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff policies should address which procedures and treatments require written informed consent. There may also be applicable Federal or State law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed. See Appendix A, SOM at tag A-0466 for more information.

Informed Consent Forms

A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- Name of the hospital where the procedure or other type of medical treatment is to take place.
- Name of the specific procedure, or other type of medical treatment for which consent is being given.
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment.
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal

representative. (Material risks could include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits, and alternatives will be discussed with the patient.)
- Signature of the patient or the patient's legal representative.
- Date and time the informed consent form is signed by the patient or the patient's legal representative.

If there is applicable State law governing the content of the informed consent form, then the hospital's form must comply with those requirements.

A well-designed informed consent form might also include the following additional information:
- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative.
- Statement, if applicable, that physicians other than the operating practitioner, including, but not limited to, residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

(See also Appendix A, SOM at tag A-0466.)

Discussion

Recent articles in both the mainstream media[2] as well as medical and scientific literature[3,4] have brought public attention to the traditional practice of allowing practitioners or supervised medical, advanced practice provider, or other applicable students to perform pelvic and other invasive examinations on patients who are under anesthesia. With this attention, patient advocates, physicians, and the students themselves have expressed concern about whether patients, especially anesthetized patients, have been sufficiently informed about this practice and whether their full consent was obtained before these educational exams were performed.[5,6]

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[2] Goldberg E. She didn't want a pelvic exam. She received one anyway. *The New York Times*. Feb. 17, 2020.
[3] *Annals of Surgery Open* 3(1):p e120, March 2022. | *DOI:* 10.1097/AS9.0000000000000120
[4] Obstet Gynecol. 2019 Dec; 134(6): 1303–1307.
Published online 2019 Nov 6. doi: 10.1097/AOG.0000000000003560
[5] Accessed at: https://www.reliasmedia.com/articles/be-careful-about-informed-consent-if-pelvic-exams-happen-while-patients-are-under-anesthesia.
[6] Accessed at: https://ny1.com/nyc/all-boroughs/news/2023/05/20/more-states-requiring-patients-to-give-consent-for-medical-students-performing-pelvic-exams

While CMS recognizes that these patient exams are often conducted as part of the vital skills clinical students must obtain during their training and education, we also firmly believe that patients have the right to make informed decisions on the healthcare services they receive so that they can give their full consent for those services including any training- and education-related examinations that may be performed in addition to any treatments or procedure that they expect to receive, especially if those patients will be under anesthesia at the time.

Therefore, we are revising our interpretive guidance in the State Operations Manual (SOM), Appendix A for hospitals at tag A-0955, to include under the example of a properly executed and well-designed informed consent form, as well as the hospital's policy and process for informed consent, the following elements (in addition to those outlined above) [new guidance in italics]:

- Whether *practitioners* other than the operating practitioner, including, but not limited to, *other physicians,* residents, *advanced practice providers, and medical and other applicable students (such as nurse practitioner and physician assistant)*, will be performing important tasks related to the surgery, *or examinations or invasive procedures for educational and training purposes*, in accordance with the hospital's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices, and placing invasive lines. *Examinations or invasive procedures conducted for educational and training purposes include, but are not limited to, breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.*

- *A written consent form is required for patients undergoing anesthesia procedures, but patients with the ability to verbally affirm consent for procedures that do not require anesthesia should have their medical record reflect that consent was given. In both instances there is written documentation of consent for any examinations.*

While CMS understands that the performance of such examinations has been necessary for teaching medical and other students critical clinical examination skills, we believe that patient permission for these exams is an essential part of the informed consent process for hospitals, and necessary for compliance with the informed consent requirements in the CMS hospital CoPs.

Contact: For questions or concerns, please contact QSOG_Hospital@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators within 30 days of this memorandum.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to specific provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.