American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

August 2, 2024

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Larry Bucshon, MD
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative DeGette and Representative Bucshon:

On behalf of the American College of Emergency Physicians (ACEP) and our nearly 40,000 members, thank you for the opportunity to respond to your recent request for information regarding the impact of the 21st Century Cures Act (Cures Act) and how to build upon the successes of this important law. As you work to develop future legislative efforts to fully realize the goals of the Cures Act and Cures 2.0, we sincerely appreciate your consideration of our comments and proposals on the several items that follow below.

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Information Blocking, Patient Harms, and Unintended Consequences of the Cures Act

With respect to the Cures Act's information blocking provisions, ACEP asks you to carefully consider the unique nature of emergency medicine, particularly how the patient-physician relationship is different for emergency physicians than many other specialties and how well-intended provisions of the law have resulted in unintended but tangible harms to some of our patients. Unlike primary care or other medical specialties, emergency physicians typically have no established relationship with our patients. In many cases, our patients present to the emergency department (ED) on the worst day of their lives, and are often in severe pain, may be fearful, or are experiencing high levels of stress due to their condition(s), and are seeking treatment in a likely unfamiliar setting with an unfamiliar physician and care team. Adding to this challenge is that emergency physicians practice in a time-constrained setting that makes it difficult to establish positive relationships with patients, an innate issue that has only been exacerbated by the nationwide ED boarding and crowding crisis that leaves emergency physicians with less and less time to spend with each individual patient. As a result, emergency physicians are responsible for more patients (many of whom should be inpatients, but there are simply no inpatient beds available for them) while it becomes near-impossible for them to have conversations they would ideally have with patients about their individual test results, as those results are made instantly available to the patient.

ACEP believes that direct communication and discussion of clinical results between the ED care team and the patient/patient representative prior to patient-level access to results is a best practice in emergency care. While ACEP recognizes the value of improved patient access to medical records and the importance of reducing "information blocking," we believe that laws and regulations that lessen an ED's ability to meet this practice causes undue confusion and anxiety for patients and their advocate(s). In many instances, orders are placed while patients are in the waiting

room. This is standard practice in the current conditions of crowded hospitals and boarding patients in which emergency physicians practice. The outcome of this practice is that labs and radiology results are made available to patients *before* there is a physician-patient relationship established. The viewability of clinical results before they can be placed in context by the ED care team may increase the potential for avoidable reactionary events which may negatively affect a patient's health, threaten the wellness of the ED care team, contribute to a hostile working environment, or lead to workplace violence based on a misinterpretation of clinical results, and has caused confusion and required emergency physicians to adjust how they practice.[1]

Examples of such cases as reported by ACEP members follow below:

- *"…multiple patients with grave worry about a 'mass' or other potential wordings for neoplastic pathology [abnormal masses of tissue] that ultimately turns into nothing but preventable worry."*

- *"…multiple patients that have informed family and friends that they have had a heart attack because they have seen their troponin results as soon as they were released. Several times I have been called into the room by panicked families on why we haven't taken them to the cath lab or seen cardiology when a second set and a discussion on the realities of high sensitivity troponin and other variables that can increase the value without it being acute ischemia."*

- *"I have also had a number learn of a new cancer diagnosis from the imaging report and before I could get into the room and talk with them about it."*

- *"…some patients waiting for definitive evaluation, but we have no beds due to crowding, will leave when they perceive their results are 'normal.' Many times we've had to call these people back as their presentations were otherwise concerning, and the initial labs sent are a subset screen of what we need."*

- *"…patient found out about her fetal demise sitting in a wheelchair in the hall outside ultrasound waiting for transport back to the ER. We try to be gentle and give patients and families privacy when we deliver news like 'your very wanted pregnancy is over.' This was a woman alone in a public waiting area crying to a poor 19 year old transporter."*

- *"More times than I can count, by the time I get into the room to explain a patient's results, the patient has already worked themselves into an existential, life-threatening dread over all of the "abnormal results" and "red flags" from their results. Almost every time, each of these "abnormal / red flags" are in fact normal for the patient, unchanged from prior, clinically insignificant or completely irrelevant to their presentation. Rather than simply being able to reassure the patient about their reassuring workup, I have to spend significant unnecessary time explaining each flagged/normal result and trying to reestablish trust and understanding that was shattered by the patient seeing their results before I can explain them and completely devoid of medical knowledge or context. The EASY fix, is to allow me to click a button to release results to the patient immediately after I've had a chance to speak to them and explain. This will avoid countless occurrences and hours of unnecessary worry, lost trust and spend more time with each new patient that walks through the front door."*

- *"A female patient who recently beat metastatic liver cancer was waiting for a CT of the chest to rule out blood clots in the lungs due to several days of shortness of breath. The CT resulted as negative but there was a comment in the body of the report that "several subcentimeter lung nodules unchanged from prior scans." I was unable to discuss the CT with the patient for several hours due to being busy with multiple critical patients. I get called back to the room by the nurse, telling me that the patient is suddenly inconsolable and endorsing thoughts of suicide. After speaking with the patient, I learned that she has trauma related to prior mistrust of the healthcare system. She saw the note about the pulmonary nodules in her patient portal and thought that this meant she has lung cancer. She believed that since they were called stable from prior scans (not previously mentioned on prior scans), the oncologists hid her recurrence of cancer from her. She expressed to me that this was such a shock to her that she did not want to be alive anymore. If I had been able to discuss these findings with the patient in a controlled setting, I would have explained that the size of these nodules made them likely to be benign and the stable nature also meant that they were benign."*

[1] https://www.acepnow.com/article/tips-for-adjusting-to-the-new-cures-act-rules-in-emergency-departments/?singlepage=1

- *"The patient saw a radiology CT report that said the appendix was not visualized. They left the waiting room, and we were unable to contact them. The patient misunderstood the significance of RLQ stranding and inflammatory changes. A surgical consult had already been ordered, but the patient left. They returned 3 days later in septic shock from a ruptured appendix. The patient was asked why they left, and he said – they did not see my appendix, so I figured I had food poisoning. He had major complications and nearly died. 2. New cancer diagnosis. There have been multiple cases where the patient knew of an imaging abnormality, where I walked into the room, and they were in tears."*

- *"…the ones that are the most challenging are fetal demise or unwanted pregnancies that patients find out on their phone in the hallway that's overcrowded. I have seen patients get up and leave, try to harm themselves as alternatives to their perceived diagnosis, and even throw things at us as staff without an understanding of what is happening. I will echo the above story about troponins, there was someone in our group that was threatened to be sued for not activating the cath lab with positive trops; we all knew there was more to the story but the family was on the phone with the lawyer in the waiting room before anyone could have a reasonable conversation with them. I support released results to patients, but at the end of the day or the morning after especially in the ED could be helpful in preventing these horrible events from happening."*

- *"I had a 37 year old female learn about her metastatic ovarian cancer via a portal message. I was on the phone trying to arrange follow up and further testing, so it took me a while to get in to see her. By the time I had all of her workup planned, she was sobbing in the room and felt so alone. Patients deserve to have this information from physicians who can provide context and support for the next steps, not via a pop up on their phone."*

As you know, under current regulations there are limited exceptions to the information blocking provisions of the Cures Act, including an exception for "Preventing Harm,"[2] wherein an entity may "…engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met." In such cases, a physician must hold a reasonable belief that this action will substantially reduce the risk of physical harm to a patient; however, this exception is limited only to physical harm and does not extend to mental or emotional harm.

Additionally, each exception or information blocking claim is reviewed subjectively and based on the facts and circumstances of each case. It is extremely burdensome to ensure physicians are covering all contingencies to defend themselves in any type of information blocking claim against them. Not only are the information blocking provisions and exceptions complicated in and of themselves, but the provisions also overlap with existing Health Insurance Portability and Accountability Act (HIPAA) regulations, and it remains unclear what information a clinician is permitted versus required to share to receive an exception. For example, a requirement to exchange all electronic health information (EHI) with any requestor for nearly any purpose may force physicians to compromise the "minimum necessary" standard in HIPAA. ACEP supports maintaining HIPAA's minimum necessary standard, which generally requires physicians to share the minimum amount of information necessary to accomplish the intended purpose of the disclosure. There are also additional challenges and potential conflicts with state-level privacy laws regarding adolescent (as well as older) populations.[3] While many emergency physicians have helped shaped electronic health record (EHR) development and training so that it is technically possible to navigate issues regarding proxy access and prevent inadvertent disclosure of sensitive test results to parents or guardians, it is still a cumbersome process and the stakes of inadvertent disclosure are high. A system that does not automatically default to disclosure of results immediately would help prevent harms for these particular populations.

Some of this uncertainty for physicians appears to exist at the local or individual hospital level, based upon individual interpretation by hospital leadership where some systems may have a built-in delay for labs, notes, or other information. Because of the overlap with existing laws, including state privacy rules, and the technical complexity of case-by-case blocking of immediate release of sensitive test results and notes to proxies or at-risk patients, a new,

[2] https://www.healthit.gov/sites/default/files/2022-07/InformationBlockingExceptions.pdf
[3] https://pubmed.ncbi.nlm.nih.gov/35175207/

standardized, safe approach to sharing ED data would be less significantly burdensome, especially with the unsustainably high levels of crowding and boarding in emergency departments throughout the country.

Given these challenges that present uniquely within the emergency care setting, ACEP asks you to consider providing a narrow, carefully-tailored exception specific to care delivered in the emergency department that still appropriately protects our patients and ensures they have access to their medical information and receive results in a timely manner. To be clear, we share your goal and the intent of the law to protect patients from information blocking practices and to ensure greater transparency. We believe that a limited exemption would provide emergency physicians with the necessary flexibility they need to protect the physician-patient relationship and deliver potentially life-changing news in the best setting at the most appropriate time in a manner that does not conflict with information blocking protections.

ACEP policy states that a clear exception for the ED to the Cures Act should be in place that affords hospitals and EDs an efficient mechanism to delay release of these results for a minimum of 24 hours. Based on additional feedback from some of our members who have personally experienced these issues, we offer several additional proposals for your consideration:

1. An exception for emergency care based on a shorter specific time threshold (for example, 6 to 12 hours).
2. An exception for emergency care to limit release of patient records until the medical screening exam (MSE) has been completed.
3. An exception for emotional or mental harm to be included under the "Preventing Harm Exception," in addition to the existing exception for physical harm.

Additionally, perhaps a limited exception process could allow an "opt-in" option for immediate notifications in the ED for those who ask for it, with the default being a delay until discharge.

Improving and Promoting Emergency Care Research

ACEP also urges you to bolster the Office of Emergency Care Research (OECR) in the next iteration of Cures to help it fulfill its mission to carry out research activities needed to improve outcomes for patients in need of lifesaving emergency care. The emergency department serves as the "front door" to the health care system, receiving more than 150 million visits per year, with more and more of our patients older in age and arriving via emergency medical services (EMS) transport. And as you well know, the ED is the first line of response in natural disasters and public health emergencies such as the COVID-19 pandemic, as well as trauma which remains one of the leading causes of death for individuals under 45 years of age. The trans-National Institutes of Health (NIH) OECR is important to foster basic, translational, and clinical research and research training for the emergency setting.

OECR does not directly fund research grants but must instead work to coordinate and catalyze efforts within other Institutes. Additionally, since its inception the office has been moved between several different divisions, now residing under the National Institute of Neurological Disorders and Stroke (NINDS). Without a direct line of funding or sufficient recognition of the need for high-quality emergency care research, OECRs mission to improve outcomes for patients who require emergency care has been marginalized. Given the experience of the COVID-19 pandemic and the emergency department serving as the front line of the response to the greatest public health crisis of our time, it is absolutely critical to promote continued research so that we are better prepared to respond to the next pandemic, natural disaster, or other mass casualty event. Providing OECR with even a small amount of resources would significantly expand its ability carry out this vital research and we encourage you to include efforts to bolster and expand OECR's reach in future legislation.

In 2023, as the efforts to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA) were in development, ACEP also urged legislators to codify the Emergency Care Coordination Center (ECCC). The ECCC plays a vital role in supporting the Emergency Care Enterprise (ECE) encompassing pre-hospital (EMS) and hospital (emergency department and trauma) care. The mission of the ECCC is to improve coordination and integration within the ECE

and should be the primary advisor to federal agencies regarding ECE matters. As part of this suggestion, we also encouraged the ECCC to work with OECR to identify, partner, and fund research projects to assess and develop best practices that facilitate daily emergency patient care and preparation and recovery of community-centered responses to disasters and other public health emergencies. As PAHPA still needs to be reauthorized and as you continue developing the new Cures package, we urge you to include language that could help achieve this goal of integrating the ECCC and OECR.

Combating Antimicrobial Resistance

Antimicrobial resistance and the reduction of remaining effective antimicrobial armamentarium represents a critical threat to public health and the health of patients in emergency departments in the U.S. and throughout the world. Antimicrobial stewardship programs aim to optimize antimicrobial usage for clinical efficacy while minimizing adverse drug events, selective pressures that drive the emergence of resistance, and costs due to suboptimal antimicrobial use. With the growing dangers of multidrug-resistant organisms and "superbugs" already a concerning reality for the health care system, and the fact that emergency physicians are the frontline physicians for any epidemic or pandemic, ACEP supports and encourages the engagement of emergency physicians and EDs in antimicrobial stewardship at all levels.

As the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) noted in a 2021 letter to HHS Secretary Xavier Becerra, the U.S. continues to face a "…severe lack of new antimicrobial drugs." This growing deficit is exacerbated by increasing antimicrobial resistance to existing treatment options, limiting health care professionals' ability to treat infections. To help address the investment and development pipeline challenges for new antimicrobial drugs, ACEP strongly supports your efforts to include the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act as part of Cures 2.0. The PASTEUR Act would establish an innovative, subscription-based payment model for novel antimicrobials, allowing the federal government to enter purchasing contracts with companies that delinks payment from sales volume. This will help reduce risks for companies seeking to develop new antimicrobials, while also ensuring the federal government only pays for successful FDA-approved treatments that are available to patients and meet unmet antimicrobial resistance needs.

Lessons Learned from COVID-19 and Preparing for Future Pandemics

Finally, ACEP supports the provisions included in Cures 2.0 targeted at addressing pandemic preparedness, including developing coordinated national testing and response strategies for future pandemics, based on the lessons learned, and best practices developed, from the COVID-19 pandemic response, efforts to support patients with rare diseases during public health emergencies, and policies to promote and support vaccine and immunization programs.

Again, as you continue to work on this important effort to improve upon the original Cures Act and Cures 2.0, we ask for your consideration of this issue and the proposals offered above. In particular, we would welcome the opportunity to work with you, patient advocacy groups, and other interested parties to find an appropriate solution to the concerns about the law's information blocking provisions that addresses emergency medicine's unique circumstances, reflects the needs of patients and their families, and protects the physician-patient relationship. Should you have any questions, please do not hesitate to contact Ryan McBride, ACEP Congressional Affairs Director, at rmcbride@acep.org.

Sincerely,

Aisha T. Terry, MD, MPH, FACEP
ACEP President