including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *https://www.ftc.gov* to read this document and the news release describing the proposed settlement. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before January 20, 2026. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an agreement containing a consent order from Illusory Systems, Inc., doing business as Nomad (''Respondent''). The proposed consent order (''proposed order'') has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received, then decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves Respondent's software development practices. Respondent operated an online service, a token bridge, through which consumers could transfer assets to peers.

The proposed complaint alleges that Respondent claimed to keep users' assets secure, but in fact failed to implement reasonably secure software development practices. For example, the proposed complaint alleges that Respondent failed to: conduct adequate unit tests, implement a process for receiving and addressing third-party security vulnerability reports, have a Written Information Security Plan, and implement widely-known technologies that would mitigate critical loss of user funds. The proposed complaint alleges that as a result of Respondent's failures, in August 2022, hackers exploited a significant vulnerability in the token bridge and took virtually all of its assets—worth approximately $186 million. Even after Respondent recovered some assets and returned them to users, users of the bridge were left with losses that exceeded $100 million worth of assets.

The proposed complaint alleges that Respondent violated section 5(a) of the FTC Act by: (1) failing to employ reasonable and appropriate software development practices; and (2) misrepresenting that it implemented secure software development practices. The proposed order contains provisions designed to prevent Respondent from engaging in the same or similar acts or practices in the future.

Part I prohibits Respondent from misrepresenting (1) the extent to which Respondent implements reasonable and appropriate software development practices; and (2) the extent to which it secures consumers' financial assets.

Part II requires Respondent to establish and implement, and thereafter maintain, a comprehensive information security program (''Security Program'') that protects the consumers' financial assets. Part III requires Respondent to obtain initial and biennial data security assessments for ten years. Part IV requires Respondent to disclose all material facts to the assessor and prohibits Respondent from misrepresenting any fact material to the assessment required by Part III.

Part V requires Respondent to submit an annual certification from a senior corporate manager (or senior officer responsible for its Security Program) that Respondent has implemented the requirements of the Order and is not aware of any material noncompliance that has not been corrected or disclosed to the Commission. Part VI requires Respondent to return recovered assets to users and to submit a report at the conclusion of the program summarizing its compliance.

Part VII requires Respondent to submit an acknowledgement of receipt of the order, including all officers or directors and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which Respondent has delivered a copy of the order.

Part VIII requires Respondent to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. Part IX contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and all records necessary to demonstrate compliance with the order. Part X contains other requirements related to the Commission's monitoring of Respondent's order compliance.

Part XI provides the effective dates of the order, including that, with exceptions, the order will terminate in 10 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2025–0453]

CAUTI Events Among Patients With Spinal Cord Injury-Associated Neurogenic Bladder (SCI–NB); Request for Information: Reopening of Comment Period

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information (RFI).

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), is reopening the public comment period for a request for

information (RFI) that was initially published on September 8, 2025, regarding Catheter-associated Urinary Tract Infections (CAUTIs) among patients with Spinal Cord Injury-associated Neurogenic Bladder (SCI–NB). We want to understand better the burden of CAUTIs among this patient population and any implications related to reporting within the CDC National Healthcare Safety Network (NHSN) device-associated urinary tract infection (UTI) event module. This docket provides an opportunity for professionals who work with this patient population, as well as those who conduct NHSN UTI surveillance, to offer feedback related to our approach.

DATES: Comments must be received by February 2, 2026. Comments received after this date will not be considered.

ADDRESSES: Submit comments by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Comments may also be sent by mail to the attention of Henrietta Smith, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, CDC, 1600 Clifton Rd. NE, Mail Stop H16–3, Atlanta 30333

Instructions: All written submissions received in response to this document must include the agency name and docket number (CDC–2025–0453) for this activity. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov*. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate submissions. *Do not submit comments by email.*

FOR FURTHER INFORMATION CONTACT: Henrietta Smith, RN, MSN, CIC, Lead-NHSN Protocol and Training Team, Surveillance Branch, Division of Healthcare Quality Promotion, by email at *nhsn@cdc.gov*. Please include the docket number (CDC–2025–0453) and ''CAUTI events among patients with Spinal Cord Injury-associated Neurogenic Bladder (SCI–NB)'' in the subject line.

SUPPLEMENTARY INFORMATION: On September 8, 2025, CDC published a request for information in the **Federal Register** (90 FR 43187). The initial comment period closed on December 8, 2025. To allow interested parties additional time to submit comments, CDC is reopening the comment period for 45 days. CDC is committed to protecting patients and healthcare workers from adverse healthcare events and promoting safety, quality, and value in healthcare delivery. Preventing healthcare-associated infections (HAIs) is a priority for CDC and its partners in public health and healthcare. As part of this work, CDC supports surveillance of Catheter-associated Urinary Tract Infections (CAUTIs) and Non-Catheter-associated Urinary Tract Infections (UTIs) and other Urinary System Infections (USIs).

UTIs are the fifth most common type of HAI, with an estimated 62,700 UTIs in acute care hospitals in 2015. UTIs account for more than 9.5% of infections reported by acute care hospitals.[1] Virtually all healthcare-associated UTIs are associated with instrumentation of the urinary tract.

Approximately 12–16% of adult hospital inpatients will have an indwelling urinary catheter (IUC) at some time during their hospitalization, and each day the IUC remains, a patient has a 3–7% increased risk of acquiring a CAUTI.[2 3] The outcomes of CAUTIs include discomfort to the patient, prolonged hospital stays, and other serious health complications, including death.[4] It has been estimated that each year, more than 13,000 deaths are associated with UTIs.[5]

Historically, the National Healthcare Safety Network has not collected data that specifically identify which patients with CAUTI events have Spinal Cord Injury-associated Neurogenic Bladder (SCI–NB). To enhance CDC's understanding of the burden of CAUTIs in this patient population, a ''Neurogenic Bladder'' risk factor variable has been added within the NHSN application. This variable allows NHSN users to indicate whether a CAUTI event occurred in patients with SCI–NB by using specific ICD–10–CM diagnosis codes. This new variable is currently optional.

NHSN's current definition of SCI–NB is in Chapter 7–UTI Events of the Patient Safety Component (PSC) manual (*https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf*). The SCI–NB ICD–10–CM diagnosis codes are available on the NHSN UTI Events web page (*https://www.cdc.gov/nhsn/xls/SCI-NB_ICD-10-CM.xlsx*). Additionally, the ''Neurogenic Bladder'' variable is accessible within the NHSN application (*https://sams.cdc.gov/*).

Note: The ''Neurogenic Bladder'' variable will be required starting January 2026. NHSN's definition of SCI–NB will be expanded to include both traumatic and non-traumatic etiologies of spinal cord injuries also starting January 2026.

This docket provides an opportunity for professionals who work with the SCI–NB patient population, as well as those who conduct NHSN UTI surveillance, to share their perspectives and concerns, which will help inform our decisions on the ''Neurogenic Bladder'' variable in the future. The CDC is also seeking additional insights into the unintended consequences of including the SCI–NB patient population in UTI surveillance, and public comments will help guide our approach moving forward. Specifically, CDC is interested in receiving information related to the following:

1. What challenges or barriers might the required reporting of spinal cord injury-associated neurogenic bladder ICD–10–CM diagnosis codes within the NHSN application pose for your facility? How could these challenges or barriers be minimized?
2. Would your facility be able to report the necessary procedure code data within 4.5 months of the end of the quarter in which the procedure occurred? If not, why not, and what is the shortest amount of time following the end of the quarter that the complete data would be available?
3. At your facility, of the patients with spinal cord injury, what injury type or condition (ICD–10–CM diagnosis codes can be provided) is most strongly associated with CAUTIs?
4. At your facility, have patients with spinal cord injury-associated neurogenic bladder experienced harms, complications, or any other unintended consequences from efforts to monitor and prevent CAUTIs?

References

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4. Scott R. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention, 2009. Division of Healthcare Quality

Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention, February 2009.
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Noah Aleshire,
Chief Regulatory Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3482–N]

Announcement of the Approval of COLA as an Accreditation Organization for the Specialties of Clinical Cytogenetics and Radiobioassay Under the Clinical Laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of the Commission on Laboratory Accreditation (COLA) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for the specialties of Clinical Cytogenetics and Radiobioassay. We have determined that COLA meets or exceeds the applicable CLIA requirements. Consequently, we are granting COLA deeming authority for the specialties of Clinical Cytogenetics and Radiobioassay for a period of 5 years.

DATES: This notice is applicable from January 20, 2026 to January 20, 2031.

FOR FURTHER INFORMATION CONTACT: Sam Cyrus, (443) 896–4827.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under those provisions, CMS may grant deeming authority to an accreditation organization if its requirements for laboratories accredited under its program are equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). Subpart E of part 493 (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) specifies the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of COLA for the Specialties of Clinical Cytogenetics and Radiobioassay

In this notice, we approve the Commission on Laboratory Accreditation (COLA) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the specialties of Clinical Cytogenetics and Radiobioassay. We have examined the initial COLA application and all subsequent submissions to determine its accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that COLA meets or exceeds the applicable CLIA requirements. We have also determined that COLA will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of subpart R. Therefore, we grant COLA approval as an accreditation organization under subpart E of part 493, for the period stated in the **DATES** section of this notice for the specialties of Clinical Cytogenetics and Radiobioassay. As a result of this determination, any laboratory that is accredited by COLA during the time period stated in the **DATES** section of this notice will be deemed to meet the CLIA requirements for the specialties of Clinical Cytogenetics and Radiobioassay, and therefore, will generally not be subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of COLA's Request for Approval as an Accreditation Organization Under CLIA for the Specialties of Clinical Cytogenetics and Radiobioassay

The following describes the process used to determine that COLA accreditation program meets the necessary requirements to be approved by CMS and that, as such, CMS may approve COLA as an accreditation program with deeming authority under the CLIA program. In reviewing these materials, we reached the following determinations for each applicable part of the CLIA regulations:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

COLA submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. We have determined that COLA policies and procedures for oversight of laboratories performing laboratory testing for the specialties of Clinical Cytogenetics and Radiobioassay are equivalent to those required under the CLIA regulations in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. COLA submitted documentation regarding its requirements for monitoring and inspecting laboratories and describing its standards regarding data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements for laboratories out of compliance, and accreditation organization resources. We have determined that COLA's requirements for monitoring and inspecting laboratories are equivalent to those required under our regulations for laboratories in the areas of data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements for laboratories out of compliance, and accreditation organization resources. Therefore, we have determined that the requirements of the accreditation program submitted for approval are equal to or more stringent than the requirements of the CLIA regulations.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

We have determined that COLA's requirements are equal to or more stringent than the CLIA requirements at §§ 493.801 through 493.865.