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

Ref: Admin: 18-19-CLIA

EXPIRED EFFECTIVE: July 06, 2023

DATE: **July 12, 2023**

ORIGINAL POSTING
DATE: **September 28, 2018**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: ***EXPIRED*: Release of Laboratory Director (LD) and Tax Information Numbers (TIN) and Information Contained in the ASPEN Complaint/Incidents Tracking System (ACTS)**

***Memo Expiration Information*:**
Expiration date: ***July 06, 2023***

Expiration Information: ***Refer to QSO-23-09-CLIA: Release of Laboratory Director and Owner Names and Their Taxpayer Identification Numbers for current guidance.***

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) is providing additional guidance related to release of LD and TIN information as well as information contained in the ASPEN/ACTS system:

- All requests for personally identifiable information (PII) related to any LD or laboratory owner, including the individual's TIN or any other PII, must be directed to the CMS Freedom of Information Act (FOIA) Office, which will determine if the information may be disclosed.
- ACTS is considered a System of Records (SOR), and as such, information related to the intake and complainant contained in ACTS may not generally be released.

Background

CMS is providing additional guidance to State Survey Agencies (SAs) on appropriate procedures to follow if they receive certain requests for information concerning LDs or laboratory owners, including TIN. The FOIA Office will determine whether this information may be disclosed. In

many cases, this information will not be appropriate for disclosure, either under the Privacy Act or under FOIA.

CMS SAs and the Regional Offices (ROs) may also receive requests for information contained within ACTS. Form CMS-2567 must not contain any PII, apart from the name and signature of the LD or laboratory owner. PII as defined by Office of Management and Budget, Circular A-130 means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual If the Form CMS-2567 Statement of Deficiencies, is appropriately free of any other PII, the SAs may disclose the forms without further review. However, detailed information from the intake related to the allegations, and information related to the complainant are not releasable unless under a "routine use". SAs and ROs must also refer such requests to the CMS FOIA Office. The CMS FOIA Office will determine whether this information may be released. In many cases, this information will not be appropriate for release, neither under the Privacy Act nor under FOIA, and Forms will need to be redacted prior to disclosure.

Refer to S&C-11-39-ALL, published on September 6, 2011, for guidance on which survey documents the SAs may directly release. Additional guidance on the release of federal documents by the SA can also be found in Admin Memo: 07-06, published January 2, 2007. The Form CMS-2567, Allegation of Compliance, Plan of Correction, and enforcement notices can be directly released based on the guidance, including timelines, outlined in the above memoranda.

Discussion

SOR

A SOR is a group of records under the control of a federal agency from which information is retrieved by the name of an individual, or by any number, symbol, or other unique identifier assigned to that individual. All SORs must be associated with a SOR Notice (SORN), which must be published in the Federal Register in order to ensure that privacy considerations have been addressed in implementing the system and to inform the public whether and how they may access that information.

Laboratory Director, Tax Information Number (TIN)

SAs and ROs may receive requests for information about LDs, laboratory owners or tax information. If this information meets the definition of PII, its disclosure may be governed by the Privacy Act, FOIA, the Health Insurance Portability and Accountability Act's (HIPAA) Privacy Rule, or other laws or regulations.

PII concerning LDs and laboratory owners, including TINs, may be protected under the Privacy Act and FOIA. An individual must request this information through the FOIA process using the guidance found on this link: https://www.foia.gov/how-to.html. These requests must be forwarded to the CMS FOIA Office which will determine whether disclosure is permissible and appropriate.

If a request is received for a Form CMS-116, Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, the name of the laboratory director and TIN must be redacted until a determination can be made by FOIA as to the ability to release this information.

ACTS

The SAs and ROs may receive requests for information related to complaints, complainant information and laboratories' deficiencies. In most cases, this information will be found on a

completed Form CMS-2567, Statement of Deficiencies and Plans of Correction. SAs and ROs should not include PII when completing Form CMS-2567. If SAs or ROs receive responses from laboratories that contain PII, they must request that the laboratory revise and re-submit their responses without PII (SOM §6130.2).

If Forms CMS-2567 do not contain PII apart from the signature of the recipient, SAs and ROs may release them to requestors. However, if the laboratory requests redaction under the FOIA, the CMS FOIA Office will need to conduct analyses under the Privacy Act, FOIA, and possibly other laws and regulations as well. CMS FOIA must ensure that its decisions are consistent with the law, its prior decisions, and the public interest. Therefore, SAs must forward such requests to CMS to permit the FOIA Office to ensure that disclosures are permissible and appropriate.

The CMS FOIA Office must determine whether the Privacy Act permits disclosure of the requested information. While individuals may request and in most cases receive information in a SOR about themselves, other disclosures may not be made unless they fall into certain categories of requests, set out in the SORN, known as "routine uses." Media requests, for example, are not among the ACTS routine uses. CMS may grant requests for PII made by individuals' attorneys, but only if the individual has granted permission for the release and documented that permission appropriately. If the request is not consistent with any of the routine uses, CMS will not disclose any of the information covered by the Privacy Act, although data that are not relevant to identifiable individuals may still be available under FOIA.

The CMS FOIA Office will also need to determine if the request is for information in a form that would permit its disclosure. Aggregate data may be released as long as individual information cannot be identified. For example, CMS may respond to a media inquiry asking the total number of complaints received for a given time period. However, CMS will not release the names of complainants unless the nature of the request is consistent with one of the routine uses included in the ACTS SORN as published in the Federal Register.

The CMS FOIA Office may respond to a request for a completed Form CMS-2567, but if the Form contains PII, the request will first be considered under the Privacy Act, and the Form will not be released unless the request falls under a routine use. If the CMS FOIA Office determines that the Privacy Act does not permit disclosure of the Form, CMS would then analyze the request under FOIA, and if all other conditions for release are met, CMS will redact the PII and grant the release under FOIA.

General SOR Information

The SORN for ACTS may be found in the Federal Register at the following link: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0565-ACTS.pdf

More information about SORs and SORNs can be found at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/CMS-Systems-of-Records.html

If you have any questions about the privacy requirement information in this memorandum, please contact Walter Stone, CMS Privacy Act Officer, Division of Security Privacy Policy and Governance, Information Security and Privacy Group, Office of Information Technology, CMS; phone: 410-786-5357 or e-mail: walter.stone@cms.hhs.gov.

General FOIA Information

More information about CMS FOIA requirements can be found at: https://www.cms.gov/center/freedom-of-information-act-center.html

If you have any questions regarding the FOIA requirement information in this memorandum, please contact Hugh Gilmore, Director, FOIA, CMS at: 410-786-5352 or e-mail at: hugh.gilmore@cms.hhs.gov.

Contact: For CLIA questions, please contact the LabExcellence mailbox at LabExcellence@cms.hhs.gov.

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

/s/
David R. Wright

cc: Survey and Certification Regional Office Management