the Port Sector Ohio Valley (COTP) in the enforcement of the safety zone.

(c) Regulations. (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP’s designated representative.

(2) To seek permission to enter, contact the COTP or the COTP’s representative by VHF–FM radio channel 16 or phone at 1–800–253–7465. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative.

(d) Enforcement periods. This rule will be enforced from 9 a.m. until 9:00 p.m. on September 23, 2022 and September 24, 2022.

Dated: August 02, 2022.

H.R. Mattern,
Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2022–16861 Filed 8–4–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF TRANSPORTATION
Office of the Secretary

49 CFR Part 40

[Docket DOT–OST–2022–0027]

RIN 2105–AF01

Electronic Signatures, Forms and Storage for Drug and Alcohol Testing Records

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Advance Notice of Proposed Rulemaking (ANPRM); request for public comments.

SUMMARY: The Department of Transportation (DOT) requests public comment on how its regulations for conducting workplace drug and alcohol testing for the federally regulated transportation industry could be amended to allow electronic signatures on documents required to be created and utilized under the regulations, to be able to use electronic versions of forms, and to electronically store forms and data. The regulatory changes would apply to DOT-regulated employers and their contractors (“service agents”) who administer their DOT-regulated drug and alcohol testing programs. Currently, employers and their service agents must use, sign and store paper documents exclusively, unless the employer is utilizing a laboratory’s electronic Federal Drug Testing Custody and Control Form (electronic CCF) system that has been approved by the Department of Health and Human Services (HHS), DOT is required by statute to amend its regulations to authorize, to the extent practicable, the use of electronic signatures or digital signatures executed to electronic forms instead of traditional handwritten signatures executed on paper forms. This rulemaking also responds to an April 2, 2020, petition for rulemaking from DISA Global Solutions, Inc. (DISA), requesting that part 40 be amended to allow the use of an electronic version of the alcohol testing form (ATF) for DOT-authorized alcohol testing. The information received in response to this ANPRM will assist DOT in the development of proposed regulatory amendments intended to provide additional flexibility and reduced costs for the industry while maintaining the integrity and confidentiality requirements of the drug and alcohol testing regulations.

DATES: Comments on this notice must be received on or before October 4, 2022.

ADDRESSES: You may submit comments identified by Docket Number DOT–OST–2022–0027 using any of the following methods:

- Hand Delivery or Courier: West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

To avoid duplication, please use only one of these methods. See the “Public Participation and Request for Comments” portion of the SUPPLEMENTARY INFORMATION section for instructions on submitting comments, including collection of information comments for the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

FOR FURTHER INFORMATION CONTACT: Mike Huntley, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone number 202–366–3784; ODAPCwebmail@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: This ANPRM is organized as follows:

I. Public Participation and Request for Comments

A. Submitting Comments

B. Viewing Comments and Documents

C. Privacy Act

II. Legal Basis for the Rulemaking

III. Purpose of Rulemaking

IV. Adoption of an Electronic CCF

V. General Comments and Questions

VI. Specific Sections of Part 40 that would be Affected

A. Employee Drug and Alcohol Testing Record

B. Medical Review Officer (MRO) reporting of verified results

C. Substance Abuse Professional (SAP) reports

D. Electronic Alcohol Testing Form (electronic ATF)

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this ANPRM (Docket No. DOT–OST–2022–0027), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. DOT recommends that you include your name and a mailing address, an email address, or a phone number in a cover letter or an email so that DOT can contact you if there are questions regarding your submission.

To submit your comment online, go to https://www.regulations.gov/docket/DOT-OST-2022-0027/document, click on this ANPRM, click “Comment,” and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

OST will consider all comments and material received during the comment period and may initiate a proposed rule based on the comments received.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to https://www.regulations.gov. Insert the docket number, DOT–OST–2022–0027, in the keyword box, and click “Search.”
Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting the Docket Management Facility.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.transportation.gov/privacy.

II. Legal Basis for the Rulemaking


The Secretary of Transportation is required by law to “issue a final rule revising part 40 of title 49, Code of Federal Regulations, to authorize, to the extent practicable, the use of electronic signatures or digital signatures executed to electronic forms instead of traditional handwritten signatures executed on paper forms.” (49 U.S.C. 322 note). The deadline for this action is not later than 18 months after HHS establishes a deadline for a certified laboratory to request approval for fully electronic CCFs (Id.) On April 7, 2022, HHS set that deadline as August 31, 2023 (87 FR 20528). The deadline for DOT’s regulatory amendments would therefore be February 28, 2025. DOT is issuing this ANPRM now to facilitate the timely proposal and adoption of the necessary amendments to part 40 to meet the statutory deadline.

There are two additional Federal statutes relevant to the implementation of electronic document and signature requirements.

1 This provision was enacted as Section 8108 of the Fighting Opioids in Transportation Act of 2018, part of the SUPPORT for Patients and Communities Act, Public Law 115–271.

The Government Paperwork Elimination Act (GPEA), codified at 44 U.S.C. 3504 note, was enacted to improve customer service and governmental efficiency through the use of information technology. The GPEA defines an electronic signature as a method of signing an electronic communication that: (a) identifies and authenticates a particular person as the source of the electronic communication; and (b) indicates such person’s approval of the information contained in the electronic communication. Id. It also requires OMB to ensure Federal agencies provide: (a) for the option of maintaining, submitting; or disclosing information electronically, when practicable; and (b) for the use and acceptance of electronic signatures when practicable. The GPEA states that electronic records and electronic signatures shall not be denied legal effect, validity or enforceability merely because they are in electronic form. Id.

The Electronic Signatures in Global and National Commerce Act (E–SIGN), codified at 15 U.S.C. 7001–7031, was designed to promote the use of electronic contract formation, signatures, and recordkeeping in private commerce by establishing legal equivalence between traditional paper-based methods and electronic methods. The E–SIGN Act allows the use of electronic records to satisfy any statute, regulation, or rule of law requiring that such information be provided in writing, if the consumer has affirmatively consented to such use and has not withdrawn such consent. Specifically, the statute establishes the legal equivalence of the following types of documents with respect to any transaction in or affecting interstate or foreign commerce, whether in traditional paper or electronic form: (a) contracts, (b) signatures, and (c) other records (15 U.S.C. 7001(a)(1)).

In addition to these Federal statutes, the Uniform Electronic Transactions Act (UETA) is a uniform state law that was finalized by the National Conference of Commissioners on Uniform State Laws in 1999, and that has been adopted by 48 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. It provides States a framework for determining the legality of an electronic signature in both commercial and government transactions.

III. Purpose of Rulemaking

The Department’s drug and alcohol testing regulations were promulgated at a time when the ability to sign and retain official records electronically—now commonplace in many business segments—was not available. Over the course of several years, we have sought ways to reduce the paper documentation associated with the drug and alcohol testing program without compromising the integrity and confidentiality requirements of the program. In 2000, we permitted greater use of faxed and scanned computer images for reporting test results. We also permitted laboratories to send electronic reports to MROs.

From June of 2002 through March of 2003, the Department’s Office of Drug and Alcohol Policy and Compliance (ODAPC) established the Electronic Transmission and Storage of Drug Testing Information Federal Advisory Committee, in accordance with the Federal Advisory Committee Act (FACA). The purpose of the Committee was to “recommend to the Department the type and level of electronic security that should be used for the transmission and storage of drug testing information generated [under part 40].” Additionally, the Committee may examine and provide advice to the DOT related to the format and methodology used in transmitting this type of information as well as the levels and procedures to use in implementing electronic signature technology within the context of the drug and alcohol program. (67 FR 12077; March 18, 2002). The participants included representatives from the transportation industries, trade associations, labor unions, consortia/third party administrators (C/TPAs), laboratories certified by the Department of Health and Human Services, MROs, and private computer companies. The group held three open-session public meetings.

Also in 2003, we standardized the format for employers to report their Management Information System (MIS) aggregate drug and alcohol testing data, as well as the specific data collected. Before that time, each DOT Agency required different data in a different format. When creating a ONE–DOT MIS Form, we then authorized employers to submit the form via a web portal.
In 2015, we issued a final rule to allow employers, collectors, laboratories, and MROs to use the electronic version of the Federal Drug Testing CCF in the DOT-regulated drug testing program. That final rule also incorporated into the regulations the requirement to establish adequate confidentiality and security measures to ensure that confidential employee records are not available to unauthorized persons. We also included language regarding protecting the physical security of records, access controls, and computer security measures to safeguard confidential data in electronic form.

Consistent with the statutory mandate in 49 U.S.C. 322 note, we are now considering additional amendments to part 40 to permit the use of electronic signatures, forms, and records storage for drug and alcohol testing records throughout the regulations (e.g., drug and alcohol background checks, MRO reporting of verified results, SAP reports, electronic ATF), while at the same time continuing to allow paper, or hard-copy use with traditional “wet signatures.” These amendments would establish parity between paper and electronic collection and submission of information required under our regulations (and in keeping with applicable OMB regulations) by allowing further use of electronic means and methods to comply with part 40 requirements. We believe that many employers and their service agents have already instituted the use of electronic signatures, forms, and records storage for the non-DOT regulated testing that they conduct. DOT supports this transition to a paperless system and is committed to ensure that the movement to a partially, or fully electronic part 40 would establish the electronic document, and continue to aid in the efficiency through faster turnaround times for required documents. Cost savings will result through reduced printing and delivery/shipping costs. We believe this will also mitigate the longstanding problems (e.g., delays in processing times of test results, cancelling of test results etc.) associated with illegible and lost copies of paper documents.

IV. Adoption of an Electronic CCF

As stated earlier in this notice, we have continually sought ways to reduce the paperwork burden associated with drug and alcohol testing without compromising the integrity and confidentiality requirements of the program.

Initially, the CCF was only available for use in paper form. In accordance with GPEA, and in an effort to reduce the Paperwork Reduction Act (PRA) burden, HHS authorized the use of an electronic CCF for Federal workplace drug testing programs. As with the paper CCF, HHS established standards and oversight procedures to ensure the authenticity, integrity, and confidentiality of drug test information when a Federal electronic CCF is used. On May 28, 2014, the Office of Management and Budget (OMB) approved the use of both paper form CCF and an electronic CCF under the HHS Mandatory Guidelines. To permit the use of an electronic CCF in the DOT drug testing program, the DOT’s April 13, 2015, final rule expanded the definition of the CCF in part 40 to include the electronic CCF. (80 FR 19551). The final rule did not require entities to use an electronic CCF—rather, it authorized employers to utilize electronic CCFs if the laboratory they use was approved by HHS for an electronic CCF. Thus, the ODAPC final rule presented another means of compliance for all entities, as permitted under the HHS mandatory guidelines.

Similarly, we do not envision publishing a proposed rulemaking to require the use of electronic means for signatures, records, and record retention. Instead, we anticipate proposing to allow employers to use electronic means for signatures, records, record retention, and other purposes within the DOT drug testing program, and an employer could choose not to utilize electronic means in any or all of the available categories.

Implementation of the electronic CCF has improved the efficiency and accuracy of documenting the urine specimen collection process. The accuracy and legibility of the information recorded on an electronic CCF is improved over that provided on the paper CCF, as employers are able to preprint information and the testing donor is able to verify the personally identifiable information (PII) within this clearly printed information. The timeliness for the verifications and reporting of results also improved with the electronic transmission of the appropriate copies to the parties. Prior to use of an electronic CCF, the most common method of transmitting the Federal CCF was via fax, but some fax machines were able to generate better quality faxes than others, and not all collection facilities had fax machines. As a result, Federal CCF copies had to be mailed, increasing the timeframes for the testing verification and the reporting of results to employers. The paper-based process also increased the risk of lost or illegible forms.

Another advantage of the electronic CCF is that the amount of space allotted for the collector’s “remarks” is greatly increased. The collector can now enter more descriptive information for the benefit of the MRO or employer, and to document any issues, refusals to test, and other relevant information.

Just as use of the electronic CCF has improved the efficiency and accuracy of documenting the urine specimen collection process, we expect that allowing the use of electronic signatures, records, and record retention throughout the entirety of part 40 will be a significant improvement. We expect advances in workflow efficiency, cost savings, and a reduction in longstanding problems associated with drug and alcohol testing program documentation and recordkeeping, as noted above.

V. General Comments and Questions

We are initiating this ANPRM to gather information from DOT-regulated employers and their service agents regarding if and how they are already handling electronic signatures, records transmission, and records storage in their non-DOT testing programs. We request comments and information on appropriate performance standards, and on whether particular methods or performance standards have been successful or unsuccessful. Additionally, we request comments and information on whether to follow industry standards, NIST standards, or something else?

In addition, the ANPRM will allow us to use the information gathered to subsequently propose a notice of proposed rulemaking (NPRM) that considers current industry standards and practices to the maximum extent practicable in developing our own performance standards for electronic signatures and records. We anticipate significant cost savings for employers and their service agents. We do not want to cause an unreasonable increase in costs by requiring inefficient or expensive systems. Beginning this
rulemaking action as an ANPRM will help us to achieve these goals.

We want to ensure that we put forth viable minimum standards for the use of technology, so that the integrity and confidentiality requirements of the program can continue to be met. The importance of ensuring the confidentiality, integrity, and availability of the data, and limiting access to any data transmission, storage, and retrieval systems, cannot be overemphasized. Even as we amend part 40 to permit the use of electronic methods, we will retain the option for regulated entities to use a paper-based system. We recognize that many of our program participants, such as small transportation employers, may not be equipped to participate in a fully electronic system. Therefore, we seek comment on the potential, advantages, risks, ramifications, and required safeguards associated with use of electronic forms, signatures, and records in the DOT drug and alcohol testing program.

Given the above, we request information regarding the following general questions:

(1) What are the practical impacts of authorizing a fully or partially electronic system?
(2) What are the economic impacts of authorizing a fully or partially electronic system?
(3) How would confidentiality and system security be maintained to prevent against data breach and data loss?
(4) How many levels of authentication should be utilized to ensure the reliability and security of the signatures of program participants?
(5) How is the non-repudiation of a system ensured?
(6) Are there any lessons learned or shared best practices available related to paperless non-DOT regulated testing?
(7) Are there any limitations in either a paperless or electronic environment that impact program efficiency?
(8) Would moving to a paperless system involve the creation of more labels and bar codes and use of additional packaging, etc., not required in a paper-based system. If so, are there any cost and/or efficiency impacts as a result?
(9) What additional definitions would need to be added to part 40 to accommodate any electronic capabilities or a fully electronic system?

(10) What measures need to be established to ensure that, when documents are transmitted to multiple parties, each party is able to properly access and use the electronic system?
(11) Part 40 requires urine collectors and breath alcohol technicians (BAT) to prepare a memorandum for the record (MFR) when certain problems are encountered during the conduct of a drug or alcohol test under part 40. How would the MFR be created and transmitted to MROs, laboratories, and employers electronically?
(12) Part 40 requires communication between MROs and the employee’s physician regarding shy bladder situations, certain safety concerns, and opioid evaluations. Could these communications be handled electronically? If so, how?
(13) Should third parties (i.e., IT and security consultants, data management firms, etc.) play a role in maintaining electronic systems and transmitting data for employers? If so, to what degree?
(14) If records are kept electronically, and the relationship ends, how would employers ensure that they have access to their electronic records if switching recordkeeping services, or if the service agent maintaining their electronic records goes out of business? Relatedly, how can employers ensure that records are not deleted, potentially leaving the DOT program participant without the records they are required to maintain under part 40?

VI. Specific Sections of Part 40 That Would Be Affected

A. Employee Drug and Alcohol Testing Record

DOT regulations at 49 CFR 40.25 establish requirements for employers to check on the drug and alcohol testing record of employees who the employer intends will perform safety-sensitive duties. This section requires an employer, after obtaining an employee’s written consent, to maintain certain information regarding the employee’s drug and alcohol testing history from DOT-regulated employers that have employed the employee during any period during a minimum of 2 years before the date of the employee’s application or transfer. This section also requires the previous employer to maintain a written record of the information released, including the date, the party to whom it was released, and a summary of the information released. Further, the employer requesting the information required under this section must maintain a written, confidential record of the information obtained.

We note that the Federal Motor Carrier Safety Administration (FMCSA) published a final rule on December 5, 2016 (81 FR 87686) to establish requirements for the Commercial Driver’s License Drug and Alcohol Clearinghouse (Clearinghouse), a database under the Agency’s administration that contains information about violations of FMCSA’s drug and alcohol testing program for the holders of commercial driver’s licenses (CDLs). This rule was mandated by 49 U.S.C. 31306a. The Clearinghouse is a secure online database that gives employers, FMCSA, State Driver Licensing Agencies, and State law enforcement personnel real-time information about CDL driver drug and alcohol program violations, thereby enhancing safety on our Nation’s roadways.

Beginning on January 6, 2020, employers were required to conduct both electronic queries and traditional manual inquiries with previous employers to meet the 3-year timeframe, required by FMCSA’s drug and alcohol use testing program, for checking CDL driver violation histories. Beginning on January 6, 2023, once 3 years of violation data are stored in the Clearinghouse, FMCSA-regulated employers must conduct a pre-employment query of the Clearinghouse to comply with the requirements in 49 CFR 40.25 and 49 CFR 391.23(e) with respect to FMCSA-regulated employers. An FMCSA-regulated employer must continue to directly request information from the driver’s previous employers regulated by a DOT agency other than FMCSA.

We seek information regarding how the requirements in § 40.25, along with record keeping requirements, can be satisfied for employers who are not required to enter data into the FMCSA’s Clearinghouse. If part 40 is amended to authorize the use of electronic forms, signatures, and record retention, how can DOT structure regulatory provisions to protect an employee’s personal information and related drug test information?

B. MRO Reporting of Verified Results

DOT regulations at 49 CFR 40.163 require MROs to report all drug test results to the employer using either (1)

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6 In a general information security context, non-repudiation is assurance that the sender of information is provided with proof of delivery, and the recipient is provided with proof of the sender’s identity, so neither can later deny having processed the information.
a signed or stamped and dated legible photocopy of Copy 2 of the CCF, or (2) a written report that must include, at a minimum, the information listed in § 40.163(c)(1)–(9) (which includes much of the information provided on Copy 2 of the CCF). As an exception to the reporting requirements listed, the regulation permits an MRO to report negative results using an electronic data file provided that the report includes, at a minimum, (1) the information specified in § 40.163(c)(1)–(9), and (2) the MRO’s name, address, and phone number, the name of any other person reporting the results, and the date the electronic results report is released.

C. SAP Reports

DOT regulations at 49 CFR 40.311 require SAPs to provide written reports, directly to a DER, following the SAP’s (1) initial evaluation that determines what level of assistance is needed to address the employee’s drug and/or alcohol problems, and (2) follow-on evaluation that determines whether the employee has or has not demonstrated successful compliance with the conditions outlined as a result of the initial evaluation. This section requires that these written reports be on the SAP’s own letterhead (and not the letterhead of another service agent), be signed and dated by the SAP, and contain the information contained in § 40.311(c)–(e) as appropriate. SAPs are required to maintain copies of reports to employers for 5 years, and must maintain employee clinical records in accordance with Federal, state, and local laws regarding record maintenance, confidentiality, and release of information.

We seek information regarding how the requirements in § 40.311 can be satisfied if part 40 is amended to authorize the use of electronic forms, signatures, and record retention.

We also seek information on how MROs, C/TPAs, and employers currently ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems when transmitting test results. Would additional requirements be needed in any amendments to part 40?

We recognize that many occupational medical practices, hospitals and other medical groups conduct collections, perform MRO and C/TPA functions, along with their medical practices. However, the DOT drug and alcohol testing records of donors must not be combined with systems with patient medical records because only those persons with a need to know about the DOT drug and alcohol testing programs can have access to the records. Would additional requirements be needed to ensure that separate systems are maintained?
In considering the factors involved with providing for an electronic ATF in the alcohol testing program regulations, we seek specific information from affected entities and other interested parties about any impact the potential use of an electronic ATF might have.

Even though use of the electronic ATF (like the electronic CCF) would be voluntary, we are interested in discerning the cost impact and any and all factors that would need to be considered to enable use of an electronic ATF including, but not limited to: (1) necessary documentation and procedures needed to establish the electronic ATF; (2) necessary system components (hardware and software requirements); (3) compatibility of the form and associated systems between alcohol testing program participants (such as between an STT and a BAT and employer); (4) training considerations; (5) system maintenance; (6) system security (protection of an employee’s personal information and related test result); and (7) and archival and audit trail considerations.

**Conclusion**

With this ANPRM, the Department seeks input on the questions set forth above. We welcome comments on all aspects of the ANPRM, and all interested parties are encouraged to provide their views.

**Delegation**

This ANPRM is issued through authority delegated to the General Counsel through a memorandum that has been placed in the docket for the rulemaking action. (See https://www.regulations.gov/document/DOT-OST-2022-0027-0001.)

John E. Putnam,
General Counsel, U.S. Department of Transportation.

[FR Doc. 2022–16862 Filed 8–4–22; 8:45 am]