December 3, 2024

Comments Submitted to the Notice of Proposed Rulemaking

In Re: Docket No. DOT–OST–2022–0027, RIN 2105-AF01
Notice of Proposed Rulemaking, 89 FR 82957 (October 15, 2024)
Procedures for Transportation Workplace Drug and Alcohol Testing Programs

Comments Submitted Via https://www.regulations.gov/ to:
Mike Huntley
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Office of the Secretary
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Dear Mr. Huntley,

The National Drug and Alcohol Screening Association (NDASA) respectfully submits these comments in response to the Notice of Proposed Rulemaking (NPRM) published at 89 FR 82957 (October 15, 2024). NDASA appreciates this long-awaited NPRM from the Office of the Secretary (OST), which will allow, but not require electronic signatures, forms, records and signatures under the US Department of Transportation's (DOT) regulation, 49 CFR Part 40 (Part 40), "Procedures for Transportation Drug and Alcohol Testing Programs". We also appreciate that the Pipeline and Hazardous Materials Safety Administration has included its proposals to conform to requirements in Part 40 and to assist readers of the PHMSA regulation in the ability to find cross-references to Part 40. The comments made in this document are based on input from NDASA's Governmental Affairs Committee, its members, and Board of Directors.

NDASA is a non-profit professional association representing more than 6,000 private and public sector employers and service agents, who administer and manage workplace drug and alcohol testing programs both domestically and internationally. The programs administered by NDASA members are diverse. They follow the employer's respective requirements under the Omnibus Transportation

Employee Testing Act (OTETA), Part 40, and the DOT agency regulations; the Department of Health and Human Services' (HHS) Mandatory Guidelines; the Nuclear Regulatory Commission's regulations; and non-Federal/non-mandated Drug-Free Workplace Programs. NDASA's membership includes laboratories, employers' substance abuse program administrators, compliance auditors, consortia/third party administrators (C/TPA), specimen collection facilities, collectors, breath alcohol technicians, screening test technicians, laboratories, medical review officers (MRO) and substance abuse professionals (SAP) who support employers in their Drug-Free Workplace Program initiatives. NDASA, is the largest trade association representing employers and their drug and alcohol industry service agents in the United States and internationally.

NDASA is a member owned organization who has led the way for industry education, training, and consultation expertise in the drug free workplace arena through the NDASA University courses, industry specific certifications, annual conferences, pertinent webinars and NDASA publications. For example, since the issuance of the DOT's Oral Fluid Final Rule on May 2, 2023 (88 FR 27596), NDASA has trained several hundred individuals as trainers through NDASA's Train-the-Trainer course.

NDASA's members have been using electronic recordkeeping, including record creation, signature and record storage, for non-DOT records for two decades or longer. We are thrilled DOT is proposing to use electronic means for DOT-regulated processes and to "establish parity between paper and electronic collection and submission of information required". 89 FR 82959 (Oct. 15, 2024) Although electronic recordkeeping is the preferred option for many of our members, there are times when our members work in remote locations where cell service and/or internet are not always available, and paper needs to be utilized. Consequently, we applaud DOT for allowing both paper and electronic means of creating forms, signing required documents, and electronic recordkeeping. So many of the provisions proposed would be tremendously cost saving for employers and their service agents, will reduce unnecessary use of paper thereby improving environmental impact, will improve efficiency, and ultimately will benefit transportation safety.

Sections 40.3 and 40.4

NDASA supports including a new definition for "Electronic signature". We have suggestions for additions to the actual text of this definition to assist employers and their service agents in complying with the new "electronic Part 40" requirements and to maintain the legal defensibility of the new electronic Part 40.

The NPRM references the E-SIGN Act, which addresses performance standards for electronic signatures and documents and allows a Federal agency "to specify performance standards to assure accuracy, record integrity, and accessibility of records that are required to be retained." 15 U.S.C. 7004(b)(3) While section 7004(b)(3) of the E-SIGN Act discourages a Federal agency from requiring the "use of a particular type of software or hardware", a performance standard is neither a software nor a hardware. Thus, while the NPRM is broad and not overly prescriptive, we respectfully request additional language to require the use of technology consistent with industry standards. This will protect Part 40 participants if future litigation ensues.

The preamble to the new Section 40.4 states foundational concepts for the creation of and signatures on electronic documents:

> Electronic documents would have a high degree of forensic defensibility as long as any changes made to the document are in the document's electronic footprint, which shows when the document or signature, as applicable, was created; when, and if, changes were made; who made the changes; and when, as applicable, a document was transmitted to and received by the receiving entity. 89 FR 82959

Although it is well-stated in the preamble, the language regarding the "electronic footprint" does not appear in the rule text of Sections 40.3 or 40.4. The DOT has made an excellent point about the forensic defensibility of an electronic document, or in this case an electronic signature, with a traceable electronic footprint. The integrity of the document can be challenged if the custodian of the electronic document cannot authenticate the integrity of the document and affirmatively certify that no one altered the document without leaving a "footprint" noting when, where, and by whom the document was changed.

In addition, the preamble stated:

> Commenters [to the ANPRM] supported the use of performance standards instead of technology-specific standards to ensure that, once established, standards do not become obsolete given the rapidly evolving nature of information technology standards and practices. 89 FR 82960

However, performance standards were not articulated in the new definitions in Section 40.3 or in the new Section 40.4. Section 7004(b)(3) of the E-SIGN Act further reinforces the use of industry performance standards providing a way to "assure accuracy, record integrity, and accessibility of records that are required to

be retained." 15 U.S.C. 7004(b)(3) We agree with DOT's rationale and the E-SIGN Act and would like to suggest supportive final rule language.

The final rule preamble could explain that a regulated-employer or service agent can rely on any industry standards they can document, if challenged. For example, Substance Abuse Professionals (SAPs) would rely on the industry standards for recordkeeping (just as 49 CFR Section 40.291(a)(1)(ii) requires remote evaluations by SAPs to meet "the level expected by industry standards"). In this final rule, any employer or service agent should be required to follow the level expected by "industry standards". In practicality, those industry standards could be those of the banking industry, the cybersecurity industry, the standards of the International Organization for Standardization (ISO), etc.

To accomplish this in Section 40.3, we respectfully suggest the following updated language in italics to be added to the definition of "Electronic signature":

> A method of signing an electronic communication that identifies and authenticates a particular person as the source of the electronic communication and indicates such person's approval of the information contained in the electronic communication, in accordance with the Government Paperwork Elimination Act (Pub. L. 105–277, title XVII, secs. 1701– 1710, 112 Stat. 2681–749, 44 U.S.C. 3504 note). *The technology for an electronic signature allowable under this part must provide integrity for the electronic signature at the level expected by industry standards, which includes showing when the document or signature, as applicable, was created; when, and if, changes were made; who made the changes; and when, as applicable, a document was transmitted to and received by the receiving entity.*

NDASA supports the proposed new definition of "written or in writing." This definition will add clarity to current practices of paper-only becoming allowable as electronic or paper practices without extensive changes to the rest of Part 40 and the Office of Drug and Alcohol Policy and Compliance (ODAPC)'s guidance materials.

It is clear DOT is making electronic retention of records allowable in this rulemaking. However, it would be helpful to have language to address documents created on paper and stored electronically. To resolve the question of whether an original paper copy of a document can be destroyed after it is stored as an electronic document in Part 40, we are requesting additional language in Section 40.4(b), as set forth below in italics.

The E-SIGN Act requires an electronic record accurately reflects the information set forth in the document and that the electronic record must remain accessible to all persons who are entitled to access by this part for the period required, in a form capable of being accurately reproduced for later reference, whether by transmission, printing, or otherwise. 15 USC 7001(d). NDASA respectfully requests such language be added to the new Sections 40.4(d) and 40.4(d)(1) as included in italics below.

In the new Section 40.4, for the reasons stated above regarding the need for an electronic footprint for forensic defensibility, and the reference to industry standards for legal defensibility, NDASA respectfully requests the following italicized changes to proposed Sections: 40.4(b), 40.4(c)(2), 40.4(d), 40.4(d)(1); and 40.4(e):

> § 40.4 May electronic documents and signatures be used?
>
> (b) Electronic records or documents. Any person or entity required to generate, maintain, or exchange and/or transmit documents to satisfy requirements in this part may use electronic methods to satisfy those requirements, *as long as those methods provide the level of integrity for the record or document expected by industry standards, including showing when the document or signature, as applicable, was created; when and if changes were made; who made the changes; and when, as applicable, a document was transmitted to and received by the receiving entity. Once an original paper document becomes an electronic record by the above-described electronic means, the paper copy can be destroyed.*
>
> (c)(2) Any available technology *that is consistent with industry standards* may be used that satisfies the requirements of an electronic signature as defined in § 40.3.
>
> (d) Electronic document requirements. Any person or entity may use documents signed, certified, generated, maintained, or exchanged using electronic methods *consistent with industry standards*, as long as the documents accurately reflect the information otherwise required to be contained in them *and include the capability to show when the document or signature, as applicable, was created; when and if changes were made; who made the changes; and when, as applicable, a document was transmitted to and received by the receiving entity*. *The electronic record must accurately reflect the information set forth in the document and must remain accessible to all persons who are entitled to access by this part for*

the period required, in a form that is capable of being accurately reproduced for later reference, whether by transmission, printing, or otherwise.

(1) Records, documents, or signatures generated, maintained, or exchanged using electronic methods *consistent with industry standards* satisfy the requirements of this section if they are capable of being retained, are used for the purpose for which they were created, *remain accessible to all persons who are entitled to access by this part for the period required,* and can be accurately reproduced within required timeframes for reference by any party entitled to access.

(e) Confidentiality and security. When using electronic documents and signatures, adequate confidentiality and security measures must be established to ensure that confidential employee records are not available to unauthorized persons. This includes protecting the *transmission of and* physical security of records, access controls, and computer security measures *consistent with industry standards* to safeguard confidential data in electronic form to include protecting against destruction, deterioration, and data corruption.

In section 40.4(e), NDASA respectfully requests the words "transmission of and" be added to ensure that any transmission of electronic records under Part 40 be sent securely, with access controls, etc. This avoids the need to add the words to sections 40.79, 40.97, 40.111, 40.127, 40.129, 40.163, 40.167, etc.

NDASA has a separate concern regarding the consent provision in section 40.4(d)(2) that could result in an otherwise compliant Part 40 collection being overturned by a decisionmaker if the donor asserts, they did not specifically provide "electronic consent." The E-SIGN Act provides a very important provision regarding the failure to obtain electronic consent or confirmation of consent that is missing from section 40.4(d)(2). Specifically, 15 U.S.C. section 7001(d)(3) states:

The legal effectiveness, validity, or enforceability of any contract executed by a consumer shall not be denied solely because of the failure to obtain electronic consent or confirmation of consent by that consumer…

This provision is similar in intent to the provisions currently in Part 40 indicating an administrative error does not constitute grounds for overturning a Part 40 result. A failure to give or obtain electronic conformation or the failure to receive confirmation of consent is not a flaw that would impact the accuracy or fairness of the test. As such it should not be the basis for overturning a Part 40 test result.

Consequently, NDASA respectfully requests the following change to the proposed 49 CFR section 40.4(d)(2) to preserve records or documents electronically signed under Part 40 from being overturned simply due to the lack of express consent:

> 40.4(d)(2) Records or documents generated electronically satisfy the requirements of this section if they include proof of consent to use electronically generated records or documents, as required by 15 U.S.C. 7001(c). *However, per 15 U.S.C. 7001(c)(3), the legal effectiveness, validity, or enforceability of any records or documents under this part must not be denied solely because of the failure to obtain electronic consent or confirmation of consent by the individual signing the record or document.*

Also, regarding this consent provision, NDASA respectfully requests additional language in the rule text and in the final rule preamble to explain how this would be carried out. It is currently clear in Part 40 that no employer or service agent can request a donor to complete additional documentation that is outside the Federal Drug Testing Custody and Control Form (CCF). Specifically, 49 CFR section 40.27 states "you must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO and SAP services)." NDASA is uncertain how to reconcile the need to obtain consent from the donor without violating section 40.47 and would appreciate clarifying text in the regulation.

Section 40.25

NDASA supports the proposed changes to Section 40.25 to allow electronic signature and electronic recordkeeping. This will greatly reduce the costs of generating, sending, and receiving back 40.25 inquiries.

In addition, we would like to see an additional edit to the proposed changes to Section 40.25. Specifically, DOT suggested "it may be beneficial for both the gaining employer and the previous employer to be able to affirmatively demonstrate that the employee's written consent *and* previous testing record were sent and received." 89 FR 82961. NDASA agrees with this but did not see this change implemented in the proposed rule text. Having a requirement for both the gaining and previous employers to create and maintain the sending and receipt of these documents is easy and inexpensive at the front end – and this will replace the very costly current procedures of trying to find these documents after the fact. Since 40.25 checks are fundamental to transportation safety, we agree that this documentation of sending and receiving is essential.

Sections 40.79, 40.97, 40.111, 40.127, 40.129, 40.163, 40.167, 40.185, 40.187, 40.191, 40.193, 40.205, 40.255, 40.261, and 40.271.

In each of these sections, the proposal is to remove words about how documents are transmitted (for example, by telephone, mail, fax, courier, etc.). If the change NDASA has suggested to Section 40.4(e) is made to address the security of transmission of records, NDASA would concur with the proposed changes to these sections to remove references on the methods of transmitting the records. However, if DOT decides not to make the changes we suggested to proposed Section 40.4(e) to address the security of transmissions, we would recommend a change made to each of these provisions to ensure secure transmissions.

In addition, we respectfully request a discussion in the final rule preamble regarding the removal of words such as "fax", "email", "courier", "image," "photocopy", "mail", "secure fax machine", and "electronically" from sections 40.25(g), 40.129(b)(2), 40.167(c)(1), 40.185(c)(1), 40.191(d) 40.205(b)(1)-(2), 40.255(a)(5)(i), 40.261(c) and 40.271(b)(2). The preamble to the NPRM stated these words were no longer needed because of the new proposed definition of "written or in writing." We would appreciate a similar discussion in the final rule preamble to clarify that faxing, sending by courier, photocopying, email, etc., are all permitted but do not need to be explicitly stated. Presumably, all Part 40-related communications would need to be by secure transmission. That may be a useful point to further underscore in this part of the final rule preamble.

Section 40.365

In concept, NDASA supports the addition to the grounds for issuing a PIE in the situation of a service agent failing to provide or maintain a secure/confidential electronic system. It would be helpful if there could be more clarity to what the enforceable measurement would be for a secure electronic system and/or a confidential electronic system. We respectfully submit that clarity would be achieved if ODAPC adopts the changes we suggested to the definition of "Electronic signature". Those changes would mean that every service agent would need to substantiate their electronic system through articulable industry standards and an electronic footprint. In the absence of these requirements, the proposed Section 40.365 would likely be unenforceable.

Sending and Receipt Confirmation – Sections 40.25, 40.191(d), 40.261(c)(1) and 40.225(a)(5)(i)

ODAPC has asked for public comment "regarding confirmation of receipt in the sections discussed above (or in other part 40 requirements) … whether it may be

beneficial or advisable to do so, and if so, for which specific sections of part 40." 89 FR 82961. NDASA supports this concept for Section 40.25 above and we would similarly appreciate comparable provisions elsewhere in Part 40.

First, it is important to note there is no current significant cost to sending an electronic document with a return receipt request that would demonstrate acceptance by the party to whom the document was sent. Taking this additional step when the document is sent saves time and money on the "back-end" where the receipt of the document is difficult for the sender to confirm after the fact. The back-end work currently involves phone calls, emails, etc. to the recipient, in order to confirm receipt after the fact. The later this confirmation must be done, the more time it can take to sort through records and find/confirm receipt.

NDASA respectfully requests a sending and confirmation receipt for the provisions in Sections 40.191(d) and 40.261(c)(1). Additionally, the sections that already require collectors to report the facts concerning suspected refusals to employers for determination of whether a refusal occurred at the collection site should also include a requirement to document the sent message by the collector and the receipt by the employer.

In addition, NDASA would support sending confirmation and receipt confirmation for the transmission of alcohol results. NDASA members have shared there are situations in which an alcohol testing violation occurred but the paper Alcohol Testing Form (ATF) showing the violation gets altered and is reported to the employer as a negative result. Since there is not a laboratory that receives the alcohol specimen and an MRO who matches the result to the identity of the donor, the Breath Alcohol Technician (BAT) and the Screening Test Technician (STT) play a larger role in alcohol testing. Allowing electronic ATFs and requiring the BAT or STT to send a result with a return receipt to show the alcohol test result was conveyed to the Consortium/Third Party Administrator or to the employer, as appropriate, would be an improvement for transportation safety.

To achieve these goals in all these provisions, simple language could be inserted. For example, each provision could include the following sentence: "*When sending the required information to the employer and/or C/TPA, as appropriate, the method of delivery must include an acknowledgement showing the name of the recipient and date of receipt."*

Other Part 40 Provisions

As you know, NDASA has been educating employers and service agents about DOT's oral fluid final rule that took effect June 1, 2023. In doing so, we have been

working with Part 40's oral fluid provisions and have noticed a few areas that have raised questions among our trainers and our trainees. We would like to request some minor changes to Part 40 that would have a minimal cost, if any.

Donors Who Are Unable to Open Their Mouth

Section 40.72(a)(2) addresses how an oral fluid collector should handle the situation when "the employee claims he or she has a medical condition that prevents opening his or her mouth for inspection." Specifically, this provision says, "the collector follows the procedure described in § 40.193(a)". However, Section 40.193(a) actually does not address this and only addresses the process when an employee has not provided a sufficient specimen. Section 40.193(a) requires the collector to attempt the collection again. If the employee has a medical condition preventing them from opening their mouth for inspection, the collector is not qualified to assess the medical situation. It would be a better solution for the collector to contact the DER to see if an alternate methodology for collection would be acceptable, or to inform the DER of the alleged medical situation and allow the DER to follow the medical referral process in Section 40.193(c). NDASA respectfully requests the following italicized revision to Section 40.72(a)(2):

> If the employee claims that he or she has a medical condition that prevents opening his or her mouth for inspection, the collector follows *the standing order to move to an alternate methodology of collection (i.e., urine). If there is no standing order addressing this scenario, the collector should contact the DER to ask if the employer prefers an alternate methodology of collection or if the employer chooses to move to the medical referral process in § 40.193(c).*

If this change to section 40.72(a)(2) is made, we recommend revising Section 40.193(c) as follows:

> As the DER, if the collector informs you that the employee has not provided a sufficient amount of specimen (*see* paragraph (b) of this section) *or if the employee says they have a medical condition that prevents opening of the mouth for inspection*, you must, after consulting with the MRO, direct the employee to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the employee's *inability to open the mouth*, failure to provide a urine (*see* paragraph (b)(1) of this section) or oral fluid (*see* paragraph (b)(2) of this section) sufficient specimen, *but not more than one of these conditions* ~~both~~. The evaluation and MRO determination required by this section only applies to the oral fluid or the

urine insufficient specimen that was the final methodology at the collection site. (The MRO may perform this evaluation if the MRO has appropriate expertise.)

If these changes are made, it would be very helpful to collectors and to DERs who face a situation of a medical condition they cannot professionally assess. Since Section 40.72 already refers to Section 40.193, we do not think there would be any additional costs related to this change.

Changing Methodologies During a Collection Should Only Happen Once

In Section 40.193(c), it is clear an MRO only needs to make a determination about the oral fluid or the urine insufficient specimen that was the final methodology at the collection site. However, how many times can there be a change in the methodology while the donor is at the collection site?

During NDASA's oral fluid train-the-trainer courses and the development of oral fluid collector training, we have received many hypothetical questions about how many times a methodology can be changed. For example, a donor comes in for a random test and the standing order requires that to be a urine test. The donor provides a specimen and hands foaming blue urine to the collector. The standing order says situations that would trigger a direct observation will become an oral fluid test. The qualified oral fluid collector would then begin an oral fluid collection but after 15 minutes, there is an insufficient specimen. The standing order says an insufficient oral fluid specimen needs to switch to urine.

We don't think DOT wants such a loop of repeating methodologies to occur. Thus, we respectfully request regulatory language that states a collection can change methodologies only once during the collection event (i.e., during that random testing event). We defer to DOT on where to include such language in Part 40.

We thank you for the opportunity to provide public comment on this NPRM. We applaud DOT for moving the fully "Electronic Part 40" forward and for reducing costs and improving efficiency in the drug and alcohol testing industries.

Respectfully Submitted,

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