Subpart G: Laboratories Certified by the Department of Health and Human Services

26.151 Purpose

This section of the final rule imposes no incremental cost and affords no saving because it merely states that the purpose of this Subpart is to present requirements pertaining to HHS-certified laboratories used by licensees and C/Vs for specimen validity and drug testing.

26.153 Using certified laboratories for testing urine specimens

Paragraph 26.153(a)

This paragraph of the final rule revises former requirements in § 26.24(f) and Sections 1.1(3), 2.7(l)(1), and 4.1(a) in Appendix A to Part 26, which authorized licensees to use only HHS-certified laboratories to perform urine drug testing, except for initial drug tests conducted at a licensee's testing facility as permitted by § 26.24(d)(2). This final paragraph only authorizes the use of HHS-certified laboratories that have the capability at the same location to perform drug testing and specimen validity testing except for initial drug and validity testing that may be performed at a licensee's testing facilities, as allowed by § 26.31(d)(3)(ii). These requirements impose no incremental cost and afford no saving because HHS-certified laboratories are already qualified to conduct validity testing (the incremental costs associated with validity testing are discussed in § 26.161(b)(1)-(5)).

Paragraph 26.153(b)

This paragraph of the final rule revises former requirements in Section 2.7(l)(2) in Appendix A to Part 26, which directed licensees to use only HHS-certified laboratories that had the capability at the same location to conduct both initial and confirmatory testing for the drugs required in Part 26. The final paragraph requires that HHS-certified laboratories must also have the capability to perform initial and confirmatory tests for specimen validity. These requirements impose no incremental cost and afford no saving because HHS-certified laboratories already have this capability and have been conducting validity testing for U.S. DOT-regulated entities.

Paragraph 26.153(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(k) in Appendix A to Part 26, which prohibited HHS-certified laboratories from subcontracting work unless authorized by the licensee. This paragraph clarifies that this restriction also applies to HHS-certified laboratories used by other entities who have licensee approved FFD programs.

Paragraph 26.153(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 4.1(b) in Appendix A to

Part 26, which pertained to the use of HHS-certified laboratories when conducting drug testing beyond Part 26 requirements.

Paragraph 26.153(e)

This paragraph of the final rule clarifies and amends former requirements in Section 2.7(m) in Appendix A to Part 26, which required licensees to conduct a pre-award inspection and evaluation of the procedural aspects of a laboratory's drug testing operation before awarding a contract to the laboratory. The final paragraph clarifies that pre-award inspections and evaluations must be conducted by qualified personnel. Also, the final paragraph adds a provision allowing licensees to immediately begin using the services of a second HHS-certified laboratory without first conducting a pre-award inspection if the licensee's first laboratory loses its certification and the second laboratory is already conducting drug and validity testing for another licensee or other entity subject to 10 CFR Part 26. Incremental savings will result from the elimination of pre-award inspection and evaluation costs for FFD programs that need to replace a decertified laboratory with a new HHS-certified laboratory that is already in use by another FFD program.

The *annual saving per FFD program* is estimated as follows:

$$HOURS_{inspection} \times WAGE_{FFD\ manager} \times PER_{decertification} \times PER_{known\ HHS\ lab}$$

Parameter	Description
$HOURS_{inspection}$	Hours per pre-award inspection of an HHS-certified laboratory conducted by licensee personnel or a designee (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$PER_{decertification}$	Percentage of FFD programs that must change to a new HHS-certified laboratory per year because their current HHS-certified laboratory loses its certification (as discussed in the assumptions below)
$PER_{known\ HHS\ lab}$	Percentage of instances in which a replacement HHS-certified laboratory is being used by another FFD program (also identified in this analysis as a "known" HHS lab) (as discussed in the assumptions below)

Assumptions:

- Hours per pre-award inspection: 100 hours, assumed to be the FFD manager.
- Each FFD program only contracts with one HHS-certified laboratory for testing services.
- Percentage of FFD programs that must change to a new HHS-certified laboratory per year because their current HHS-certified laboratory loses its HHS-certification or withdraws from the certification program: 10 percent.
- Percentage of instances in which a replacement HHS-certified laboratory is

already in use by another FFD program (also identified in this analysis as "known" HHS-certified laboratory): 50 percent.

Paragraph 26.153(f)

This paragraph of the final rule restates former requirements in Section 2.7(m) in Appendix A to Part 26, which mandated that licensees require their HHS-certified laboratories to implement and comply with all applicable requirements in Part 26.[1] The final subparagraphs specify the minimum contractual terms between a licensee or C/V and their HHS-certified laboratory as discussed below:

- Subparagraph 26.153(f)(1) restates former requirements in Section 2.7(l)(1) in Appendix A to Part 26.

- Subparagraph 26.153(f)(2) clarifies former requirements in Section 2.7(o)(5) in Appendix A to Part 26.

- Subparagraph 26.153(f)(3) clarifies former requirements in Section 3.1 in Appendix A to Part 26.

- Subparagraph 26.153(f)(4) clarifies former requirements in Section 3.2 in Appendix A to Part 26.

- Subparagraph 26.153(f)(6) clarifies former requirements in Section 2.7(m) in Appendix A to Part 26.

Paragraph 26.153(f) of the final rule also adds one new contract term as discussed below:

- Subparagraph 26.153(f)(5) prohibits HHS-certified laboratories from entering into any relationships with a licensee's or other entity's MRO when such relationships may be construed as potential conflicts of interest. Although this is a new requirement, it is consistent with ethical business practices and Section 2.4(g)(6) in the HHS Guidelines (April 13, 2004). Consequently, although programs may incur an incremental cost to revise certain contracts to incorporate the new provision, such costs would fall only on programs with contracts that (a) do not already contain such a provision, and (b) will not update themselves automatically by incorporating the NRC provisions "by reference." The analysis assumes that any costs resulting from this provision are reflected within the legal and managerial costs calculated for § 26.27(a).

Paragraph 26.153(g)

[1] HHS-certified laboratories will pass on the costs associated with specific rule revisions to licensees through increased specimen testing costs. The analysis accounts for these incremental costs associated with implementation of validity testing requirements in § 26.131(a) and § 26.161(b), the most significant testing change in the final rule.

This paragraph of the final rule adds a requirement that licensees and other entities must provide their HHS-certified laboratory with an explanatory memorandum for the record in situations where a non-Federal custody-and-control form is used for a specimen collection. The memorandum must describe why the form is being used and must state that the form contains all information required in the Federal custody-and-control form. Incremental costs per FFD program result from the labor costs of collection site personnel to write each memorandum.

The *annual cost per FFD program* is estimated as follows:

$$[NUM_{memoranda} \times (HOURS_{collector} \times WAGE_{collector})] \times NUM_{facilities}$$

Parameter	Description
$NUM_{memoranda}$	Number of memoranda per year a collection site used by a facility will write because it uses a non-Federal custody-and-control form for a specimen collection (as discussed in the assumptions below)
$HOURS_{collector}$	Time for collection staff to draft a memorandum(as discussed in the assumptions below)
$WAGE_{collector}$	Wage of collection site personnel (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of memoranda per year a collection site used by a facility will write because it uses a non-Federal custody-and-control form for a specimen collection: 2.

- Time for collection staff to draft a memorandum: 15 minutes.

26.155 Laboratory personnel

Paragraph 26.155(a)

The final paragraph restates without substantive change a former requirement in Section 2.5(a)(1) in Appendix A to Part 26. The final rule replaces the term "qualified individual" used in the former rule with the term "responsible person." Subparagraphs (a)(1)–(6) in the final rule restate the former requirements in Sections 2.5(a)(2)–(7) in Appendix A to Part 26 that defined the qualifications and responsibilities of the individual responsible for the HHS-certified laboratory's testing facility. Therefore, this final paragraph imposes no incremental costs and affords no savings.

Paragraph 26.155(b)

This paragraph of the final rule revises a former requirement in Section 2.5(b) in Appendix A to Part 26, which described the "qualified individual who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports." The final paragraph introduces the term "certifying scientist" to clarify the term "qualified individual"

used in the former rule. The final rule also establishes the qualifications for a certifying scientist. No incremental costs or savings are expected to result from this final paragraph because the qualifications for a certifying scientist are consistent with existing HHS-laboratory personnel qualification requirements.

Paragraph 26.155(c)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.5(c) in Appendix A to Part 26.

Paragraph 26.155(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.5(d) in Appendix A to Part 26.

Paragraph 26.155(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.5(e) in Appendix A to 10 CFR Part 26.

Paragraph 26.155(f)

This paragraph of the final rule simplifies former requirements in Section 2.5(f) in Appendix A to Part 26, which mandated that laboratory personnel files must include: "resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds . . ." Under the final paragraph, personnel files will no longer need to include: references, referrals, and incident reports, but must still include "a resume, any professional certification(s) or license(s), a job description, and documentation to show that the individual has been properly trained to perform his or her job." Even though the final paragraph represents a relaxation of the former recordkeeping requirements applicable to HHS-certified laboratories, the analysis assumes that laboratories will not alter their file maintenance practices (and will not incur savings) because businesses commonly maintain the aforementioned documents that are no longer required.

26.157 Procedures

Paragraph 26.157(a)

This paragraph of the final rule revises former requirements in Section 2.2 in Appendix A to Part 26, which pertained to the maintenance and documentation of procedures for collecting, shipping, and accessing urine specimens. The final rule clarifies that the HHS-certified

laboratory must also maintain procedures for receiving and testing specimens. The final paragraph imposes no incremental cost and affords no saving because it is consistent with the procedures and practices of existing HHS-laboratories.

Paragraph 26.157(b)

This paragraph of the final rule revises former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to the content and implementation of specimen chain-of-custody procedures for HHS-certified laboratories. The final rule adds a provision that the HHS-certified laboratory must have written chain-of-custody procedures for shipping specimens to another HHS-certified laboratory. The final paragraph imposes no incremental cost and affords no saving because the new requirement is consistent with the existing specimen chain-of custody procedures used by HHS-certified laboratories.

Paragraph 26.157(c)

The final paragraph revises former requirements in Section 2.7(o)(1) in Appendix A to Part 26, which required that each HHS-certified laboratory maintain a "procedure manual." The final paragraph clarifies that HHS-certified laboratories must develop, implement, and maintain a "written standard operating procedures manual." The revision imposes no incremental costs or savings because it restates without substantive change former requirements.

Paragraph 26.157(d)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change a former requirement in Section 2.7(o)(3)(iii) in Appendix A to Part 26.

Paragraph 26.157(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(o)(4) in Appendix A to Part 26, which mandated that licensee testing facilities develop, implement, and maintain procedures for remedial actions if systems do not meet acceptable limits or errors are detected.

26.159 Assuring specimen security, chain of custody, and preservation

Paragraph 26.159(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates without substantive change former requirements in § 2.7(a)(1) in Appendix A to Part 26, which pertained to laboratory security. This final paragraph provides added flexibility to security requirements by enumerating individuals who are permitted to be unescorted in an HHS-certified laboratory (e.g., personnel conducting inspections and audits on behalf of licensees, other entities, the NRC, the Secretary of the DHHS, and emergency personnel).

Paragraph 26.159(b)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements in Section 2.7(b)(1) in Appendix A to Part 26. The final rule also requires each licensee to investigate possible specimen tampering and take corrective actions when necessary. If there is a reason to believe that the integrity or identity of a specimen is in question, the specimen is not to be tested and the licensee or C/V must ensure that another collection occurs as soon as reasonably practicable. The final rule adds a provision that another collection is not required if either bottle from a split specimen collection remains intact and contains at least 15 mL of urine. In this case, the split specimen must be sent to the HHS-certified laboratory for testing. The final rule also specifies exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen. The analysis estimates that these final provisions will impose no incremental costs and afford no savings because the requirements are consistent with existing licensee practices, and because of the infrequent occurrence of specimen tampering events.

Paragraph 26.159(c)

This paragraph of the final rule revises former requirements in Section 2.7(b)(2) in Appendix A to Part 26, which pertained to the handling of urine specimens at HHS-certified laboratories and the use of internal custody and control forms. The final rule clarifies that laboratory chain-of-custody forms must be used while conducting initial and confirmatory testing of aliquots of an original urine specimen. The final rule also establishes that the original specimen and original specimen custody-and-control form must remain in secure storage. This final paragraph will impose no incremental cost and affords no saving because it is consistent with the existing urine specimen handling and storage practices of HHS-certified laboratories.

Paragraph 26.159(d)

This paragraph of the final rule revises former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to the use of internal custody and control forms by HHS-certified laboratories. The final rule expands the required information contained on the laboratory custody-and-control form to now include the identity of the donor. Adding this information to the custody-and-control form will not result in any incremental costs.

Paragraph 26.159(e)

This paragraph of the final rule restates without substantive change former requirements in Section 2.7(a)(2) in Appendix A to Part 26, which pertained to completing the custody-and-control form each time a specimen is handled or transferred within the laboratory. The final paragraph imposes no incremental cost and affords no saving because the requirements are believed to be consistent with existing specimen chain-of-custody procedures used by HHS-certified laboratories.

Paragraph 26.159(f)

The final paragraph revises former requirements in Section 2.4(d) in Appendix A to Part 26, which pertained to specimen chain of custody procedures. This final paragraph also extends to HHS-certified laboratories the specimen packaging and shipping requirements in former Section 2.4(i) in Appendix A to Part 26, which only applied to collection sites. The final paragraph imposes no incremental cost and affords no saving because it is consistent with current HHS-certified laboratory practices.

Paragraph 26.159(g)

This paragraph of the final rule clarifies that couriers, express carriers, and postal service personnel do not have access to the custody-and-control forms or to the specimen bottles and, therefore, are not required to document chain-of-custody on the custody and control form of a urine specimen in transit. However, this paragraph adds a new requirement that the custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service. The final paragraph imposes no incremental cost and affords no saving because it describes existing courier, express carrier, and postal service specimen shipping practices.

Paragraph 26.159(h)

The final paragraph imposes no incremental cost and affords no saving because it restates without substantive change former requirements in Section 2.7(c) in Appendix A to Part 26, which pertained to short-term refrigeration storage procedures of urine specimens.

Paragraph 26.159(i)

This paragraph of the final rule revises former requirements in Section 2.7(h) in Appendix A to Part 26, which specified long-term storage requirements for positive urine specimens so that they can be made available for any necessary retesting. The final paragraph adds specimens with adulterated, substituted, and invalid test results to those that already must be stored for possible further testing. The analysis assumes that the storage costs for any additional urine specimens that must be retained by the HHS-laboratory as a result of validity test results will be accounted for in the per test cost that an HHS-certified laboratory charges each licensee. Therefore, any incremental cost resulting from the final paragraph are captured in the new validity test costs estimated in connection with §§ 26.131 and 26.161(b)(1)-(5) of the final rule.

Paragraph 26.159(j)

This paragraph of the final rule establishes a new requirement that specimens testing negative on initial or confirmatory drug testing be discarded or may be pooled for use in the HHS-certified laboratory's internal quality control program, unless validity testing indicates that the specimen is invalid. The paragraph also adds a new provision that the laboratory may not retain any information linking donors to specimens pooled for use in the internal quality control program.

The final paragraph imposes no incremental cost and affords no saving because it is consistent with current practices of HHS-certified laboratories.

26.161 Cutoff levels for validity testing

Paragraph 26.161(a)

This paragraph of the final rule establishes that each initial validity test must be performed on one aliquot of a donor's urine specimen. Licensees and other entities must ensure that the HHS-certified laboratory is capable of conducting, and conducts, confirmatory testing for at least one oxidizing adulterant and any other adulterants specified by the licensee's or other entity's testing program. To report an adulterated, substituted, dilute, or invalid test result, a confirmatory validity test must be performed on a second aliquot of the donor's urine specimen. All costs associated with validity testing are considered to be incremental[2] because validity testing is a new regulatory provision. Incremental costs associated with validity testing are discussed in connection with § 26.161(b)(1)-(5).

Paragraph 26.161(b)

Subparagraphs 26.161(b)(1)-(5)

These subparagraphs of the final rule establish initial validity testing requirements, including the types of initial tests to be performed (creatinine, pH, adulterants) and the specific criteria to determine whether a specimen may be adulterated, substituted, dilute, or invalid, and thus, require confirmatory validity testing. The analysis accounts for validity testing costs under this requirement based on a per specimen testing cost at HHS-certified laboratories (i.e., initial validity testing or initial and confirmatory validity testing have the same cost).

The regulatory analysis calculates under these subparagraphs not only the costs related to conducting initial and confirmatory validity testing, but also the subsequent costs for some specimens to receive initial and confirmatory drug testing, and the associated costs resulting from confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen). Even though many of these costs are directly related to other provisions, as referenced below, this approach consolidates the series of actions that are initiated under § 26.161(b)(1)-(5), allowing for a unified (hence clearer) presentation of related actions and a simpler analysis.

FFD programs using HHS-certified laboratories for all drug testing will incur a per specimen incremental cost to conduct validity testing, as well as the labor costs of MRO and FFD

[2]By assuming that no licensees currently conduct validity testing, the analysis overstates the incremental costs to be incurred by FFD programs as a result of the validity testing provisions. This assumption is necessary, however, because of the lack of available data regarding the types of validity testing being conducted throughout the industry.

personnel for administrative activities for confirmed positive drug test results and/or confirmed adulterated or substituted validity test results, the costs of retesting some specimens with confirmed drug positive, adulterated, substituted, or invalid test results at the donor's request (MRO's request for invalid specimens), and the costs of the appeals process for some drug positive, adulterated, or substituted test results that donors choose to contest. In addition, because HHS certified laboratory testing procedures and required licensee actions vary based on the type of confirmatory validity test result (e.g., dilute, invalid), the analysis discusses the costs for each validity test result type separately (designated below as "Results A, B, and C")

- "Result A": adulterated and substituted specimens

- "Result B": dilute specimens

- "Result C": invalid specimens

Annual cost per FFD program that conducts all drug testing (and validity testing) at an HHS-certified laboratory is estimated as follows:[3]

- Cost to conduct validity testing (initial and confirmatory when necessary) at an HHS-certified laboratory:

$$NUM_{validity} \times COST_{HHS\ validity\ testing} \times NUM_{reactors}$$

- Additional testing may be required based on specific confirmatory validity test results, as described by the following result cases (Results A, B, and C).

- Result A: Specimens with HHS-certified laboratory confirmatory validity test results of adulterated or substituted (creatinine concentration less than 2 mg/dL). No additional testing procedures.

- Result B: Specimens with HHS-certified laboratory confirmatory validity test results of dilute. Additional costs include confirmatory drug testing to the limit of detection (LOD) for some specimens.[4] The costs include the following:

$$NUM_{validity} \times PER_{dilute} \times COST_{HHS\ LOD\ testing} \times NUM_{reactors}$$

- Result C: Specimens with HHS-certified laboratory confirmatory validity test results of invalid. Additional costs include collecting a second urine specimen under direct observation, as specified in § 26.185(f)(3) of the final rule, and then validity and drug testing the second specimen at an HHS-certified laboratory. The costs include the following:

[3]Incremental costs associated with validity testing for FFD programs using onsite licensee testing facilities are discussed in connection with § 26.131.

[4]Paragraph 26.163(a)(2) of the final rule permits FFD programs to require confirmatory LOD drug testing for any drug with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator.

$$NUM_{validity} \times PER_{invalid} \times [(COST_{2nd\ collection} + COST_{HHS\ validity\ \&\ drug\ testing})] \times NUM_{reactors}$$

- Cost of subsequent actions for all adulterated, substituted, dilute, or invalid validity test results and positive drug test results identified because of the validity testing requirements in § 26.161(b) and § 26.185(f)(3) (sum of adulterated, substituted, dilute, and invalid validity test results and positive drug tests from Results A, B, and C). FFD programs may also incur costs associated with some donors requesting testing of their split specimen and/or some donors appealing their positive, adulterated, or substituted validity and/or drug test results.

  - Cost for actions subsequent to confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results

$$(NUM_{validity} \times [(PER_{adulterated} + PER_{substituted}) + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2^{nd}\ collection})] \times COST_{subsequent\ actions}) \times NUM_{reactors}$$

  - When requested by some donors, the cost of retesting specimens with confirmed adulterated or substituted validity, and/or positive drug (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen) test results at a second HHS-certified laboratory

$$(NUM_{validity} \times [(PER_{adulterated} + PER_{substituted}) + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2^{nd}\ collection})] \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$$

  - When requested by some donors, the cost of the appeals process for confirmed adulterated or substituted validity and/or positive drug test results (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen)

$$NUM_{validity} \times [(PER_{adulterated} + PER_{substituted}) + (PER_{dilute} \times PER_{positive\ at\ LOD}) + (PER_{invalid} \times PER_{drug\ positive\ 2^{nd}\ collection})] \times PER_{appeal} \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + HOURS_{Worker} \times WAGE_{Worker}] \times NUM_{reactors}$$

Parameter	**Description**
$NUM_{validity}$	Number of validity tests per reactor per year (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
$COST_{HHS\ validity\ testing}$	Incremental cost per urine specimen to conduct validity testing (initial validity test and confirmatory validity test when necessary) at an HHS-certified laboratory (as discussed in the assumptions below)
PER_{dilute}	Percentage of urine specimens with validity test results of dilute (as discussed

Parameter	Description
	in Appendix 2, Exhibit A2-12)
$COST_{HHS\ LOD\ testing}$	Cost per specimen to conduct initial drug testing and confirmatory drug testing to the level of detection (LOD) for drug(s) identified during initial testing, as permitted by § 26.163(a)(2) of the final rule (as discussed in Appendix 2, Exhibit A2-13)
$PER_{invalid}$	Percentage of urine specimens with validity test results of invalid (as discussed in Appendix 2, Exhibit A2-12)
$COST_{2nd\ collection}$	Cost of collecting a second urine specimen under direct observation from a donor with a confirmatory validity test result of invalid for the initial urine specimen collected. The cost of the second collection includes the labor for the donor's travel time to and from the collection site, donor's time spent at the collection site, as well as the labor of the collector (as discussed in Appendix 2, Exhibit A2-13)
$COST_{HHS\ validity\ \&\ drug\ testing}$	Cost per specimen to conduct initial drug and initial validity testing at an HHS-certified laboratory, as well as confirmatory drug and/or validity testing when necessary (as discussed in Appendix 2, Exhibit A2-13)
$PER_{adulterated}$	Percentage of urine specimens with validity test results of adulterated (as discussed in Appendix 2, Exhibit A2-12)
$PER_{substituted}$	Percentage of urine specimens with validity test results of substituted (less than 2 mg/dL creatinine) (as discussed in Appendix 2, Exhibit A2-12)
$PER_{positive\ LOD}$	Percentage of dilute specimens that test positive for drug(s) at LOD testing (as discussed in the assumptions below)
$PER_{drug\ positive\ 2nd\ collection}$	Percentage of specimens collected under direct observation as a result of an initial specimen with a confirmatory validity test result of invalid that test positive for drugs (as discussed in the assumptions below)
$COST_{subsequent\ actions}$	Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result (as discussed in Appendix 2, Exhibit A2-13)
PER_{retest}	Percentage of urine specimens with confirmed positive, adulterated, substituted, dilute, or invalid validity and/or drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below)
$COST_{retest}$	Cost of specimen retesting at a second HHS-certified laboratory, including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
PER_{appeal}	Percentage of confirmed adulterated and substituted validity test results and positive drug test results appealed by some donors (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Average amount of FFD manager time per appeal for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or

Parameter	Description
	adulterated or substituted validity test result appealed by some donors (as discussed in the assumptions below)
$WAGE_{FFD\ manger}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{Worker}$	Average amount of worker time per appeal of a confirmed adulterated or substituted validity test result and/or positive drug test result (as discussed in the assumptions below)
$WAGE_{Worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of validity tests per reactor per year is equivalent to the number of drug tests conducted by each reactor per year.

- Each FFD program contracting with an HHS-certified laboratory to conduct all drug and validity testing of urine specimens will pay a fixed cost per specimen, which will account for initial drug and validity testing and confirmatory drug and validity testing when necessary.[5]

- All FFD programs choose to test dilute specimens according to the optional provisions in § 26.163(a)(2). That is, any specimen with an initial drug test result equal to or greater than 50 percent of the cutoff calibrator will receive confirmatory LOD drug testing.

- Percentage of dilute specimens that test positive for drug(s) at LOD testing: 33 percent.

- All urine specimens that test as adulterated, substituted (< 2 mg/dL creatinine), or invalid on initial validity testing, remain adulterated, substituted, and invalid after confirmatory validity testing.

- For all urine specimens with validity test results of invalid, the analysis assumes that a second specimen is collected under direct observation.

- Percentage of specimens collected under direct observation as a result of an initial specimen with a confirmatory validity test result of invalid that test positive for drugs: 33 percent.[6]

[5]Some HHS-certified laboratories may not charge licensees to conduct initial and confirmatory validity testing, given the other tests that are being performed. However, to be conservative, the analysis assumes that a validity test at an HHS-certified laboratory will cost $1.50.

[6]A second specimen is collected under direct observation for donors that have an initial specimen with an invalid test result to reduce the probability that their second specimen will be altered (e.g., use of adulterants) and therefore, the drug use that was attempted to be masked during the initial specimen donation will more likely be

- Percentage of urine specimens with confirmed positive drug, and/or adulterated or substituted validity test result retested at the request of the donor at a second HHS-certified laboratory: 5 percent.

- Percentage of confirmed positive, adulterated, and substituted validity and drug test results appealed by some donors: 1 percent.

- Average amount of FFD manager time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result: 12.5 hours.

- Average amount of worker time per appeal process for a confirmed positive drug test result (including positive drug test results following confirmatory testing to the LOD for dilute specimens and positive test results following the second collection for a donor that produced an invalid specimen), and/or adulterated or substituted validity test result appealed by some donors: 2.0 hours.

Paragraphs 26.161(c), (d), (e), and (f)

The final paragraphs establish the analytical test result thresholds, which indicate that a urine specimen is adulterated, substituted, dilute, or invalid. The incremental costs associated with validity testing are discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.161(g)

This paragraph of the final rule adds a new requirement that if a urine specimen is suspected of containing an unidentified interfering substance or adulterant that could make a validity test invalid, the HHS-certified laboratory must consult with the licensee's or other entity's MRO to obtain instruction as to whether to send the specimen to a second HHS-certified laboratory that has the capability to identify the suspected substance or adulterant.

The *annual cost per FFD program* is estimated as follows:

$$NUM_{new\ adulterant} \times [COST_{retest} + (HOURS_{MRO} \times WAGE_{MRO})] \times NUM_{facilities}$$

Parameter	Description
$NUM_{new\ adulterant}$	Number of urine specimens per facility per year that are suspected of having a new adulterant or interfering agent that could make a test result invalid and the MRO

detected in the second specimen collected. (Note: the analysis assumes that if the MRO chooses to retest the initial invalid specimen at a second HHS-certified laboratory, the second laboratory will be unable to identify what is causing the specimen result to be invalid and a second specimen collection under direct observation would commence.)

Parameter	Description
	decides to send to a second HHS-certified laboratory for additional validity testing (as discussed in the assumptions below)
$COST_{retest}$	Cost per specimen to conduct validity retesting at a second HHS-certified laboratory, including specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
$HOURS_{MRO}$	Time per specimen for an MRO to speak with the HHS-certified laboratory and determine whether a specimen is to be retested at a second HHS-certified laboratory, and the time to review the results of validity testing at the second HHS-certified laboratory (as discussed in the assumptions below)
$WAGE_{MRO}$	MRO wage rate (as discussed in Appendix 2, Exhibit A2-11)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Number of urine specimens per facility per year that are suspected of having a new adulterant or interfering agent that could make a test result invalid and the MRO decides to send to a second HHS-certified laboratory for additional validity testing: 1.

- Time per specimen for an MRO to speak with the HHS-certified laboratory and determine whether a specimen is to be retested at a second HHS-certified laboratory, and the time to review the results of validity testing at the second HHS-certified laboratory: 30 minutes.

- MRO chooses to retest all specimens that are suspected of containing adulterants or interfering agents that could make a test result invalid.

Paragraph 26.161(h)

The final paragraph imposes no incremental cost and affords no saving because it prohibits licensees and C/Vs from using validity testing cutoff levels that are more stringent than those specified in Part 26. The costs associated with validity testing are discussed in connection with §§ 26.131 and 26.161(b)(1)-(5) of the final rule.

26.163 Cutoff levels for drugs and drug metabolites

Subparagraph 26.163(a)(1)

This subparagraph revises former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which pertained to the initial cutoff levels for drugs and drug metabolites (marijuana, cocaine, opiates, phencyclidine, amphetamines). The final rule will lower the initial cutoff level for marijuana metabolites from 100 ng/mL to 50 ng/mL. FFD programs conducting initial drug testing at HHS-certified laboratories will incur annual incremental costs attributable to the more stringent cutoff testing level, which will increase the number of positive drug tests for marijuana.

The additional costs will consist of labor costs for the MRO and FFD personnel activities resulting from confirmed positive drug test results, the costs of retesting specimens at a second HHS-certified laboratory at the request of some donors, and the costs of the appeals process for some positive test results that donors choose to contest. The final rule will also raise the initial cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL. FFD programs conducting initial drug testing at HHS-certified laboratories will realize annual incremental savings resulting from the less stringent cutoff level, which will significantly reduce the number of positive opiate drug tests that MROs will ultimately verify as negative. Incremental savings will result from eliminating labor costs associated with the MRO and FFD personnel activities as a result of fewer confirmed positive drug test results, savings associated with fewer donors requesting retesting of their specimen at a second HHS-certified laboratory, and the savings from fewer appeals for some positive drug test results that donors choose to contest.

Annual cost per FFD program using HHS-certified laboratories for initial drug testing for additional confirmed positive marijuana drug test results is estimated as the sum of the following:

- Cost for actions subsequent to additional positive confirmatory marijuana drug test results:

  $(NUM_{marijuana} \times PERI_{marijuana} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Cost for retesting specimens with confirmed positive marijuana drug test specimens at a second HHS-certified laboratory at the request of some donors:

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Cost of appeals process for confirmed positive marijuana test results that some donors choose to contest:

  $(NUM_{marijuana} \times PERI_{marijuana} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + HOURS_{worker} \times WAGE_{worker}] \times NUM_{reactors}$

Annual saving per FFD program using HHS-certified laboratories for initial drug testing for fewer confirmed positive opiate drug tests is estimated as the sum of the following:

- Saving from fewer specimens with positive confirmatory opiate drug test results:

  $(NUM_{opiate} \times PERD_{opiate} \times COST_{subsequent\ actions}) \times NUM_{reactors}$

- Saving from fewer positive opiate drug test specimens retested at another HHS-certified laboratory at the request of some donors:

  $(NUM_{opiate} \times PERD_{opiate} \times PER_{retest} \times COST_{retest}) \times NUM_{reactors}$

- Saving from fewer appeals for confirmed positive opiate drug test results that some donors choose to contest:

$(NUM_{opiate} \times PERD_{opiate} \times PER_{appeal}) \times [(HOURS_{FFD\ manager} \times WAGE_{FFD\ manager}) + HOURS_{worker} \times WAGE_{worker}] \times NUM_{reactors}$

Parameter	Description
$NUM_{marijuana}$	Number of confirmed marijuana positive drug test results under the former rule per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PERI_{marijuana}$	Percentage increase in positive marijuana drug test results due to the more stringent cutoff level in the final rule (as discussed in the assumptions below)
$COST_{subsequent\ actions}$	Labor costs associated with MRO and FFD program personnel activities and administrative actions resulting from a confirmatory positive drug test result (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)
PER_{retest}	Percentage of urine specimens with confirmed positive drug test results which the donors request specimen retesting at a second HHS-certified laboratory (as discussed in the assumptions below)
$COST_{retest}$	Cost of specimen retesting at a second HHS-certified laboratory, including specimen preparation and shipping costs, per specimen (as discussed in Appendix 2, Exhibit A2-13)
PER_{appeal}	Percentage of confirmed positive drug test results appealed by some donors (as discussed in the assumptions below)
$HOURS_{FFD\ manager}$	Average amount of FFD manager time per appeal of a confirmed positive validity test result (as discussed in the assumptions below)
$WAGE_{FFD\ manager}$	FFD manager wage rate (as discussed in Appendix 2, Exhibit A2-11)
$HOURS_{worker}$	Average amount of worker time per appeal of a confirmed positive drug test result (as discussed in the assumptions below)
$WAGE_{worker}$	Facility worker wage rate (as discussed in Appendix 2, Exhibit A2-11)
NUM_{opiate}	Number of confirmed positive opiate drug test results under the former rule per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
$PERD_{opiate}$	Percentage decrease in positive opiate drug test results due to the higher cutoff level in the final rule (as discussed in the assumptions below)

Assumptions:

- Percentage increase in positive marijuana drug test results due to the more stringent cutoff level in the final rule: 40 percent.[7]

- Percentage of urine specimens with confirmed positive drug test results which the

[7]When U.S. DOT changed the marijuana metabolite cutoff level from 100 ng/mL to 50 ng/mL, HHS-certified laboratories experienced an increase in the number of positive marijuana test results from 25 to 40 percent. Several licensees currently test for marijuana metabolites at the 50 ng/mL cutoff level, as required in the final rule. One licensee reported 49 additional positive test results over a 2½-year period (an increase of 57 percent over the 100 ng/ml cutoff level).

donors request specimen retesting at a second HHS-certified laboratory (as discussed in the assumptions below): 5 percent.

- Percentage decrease in positive opiate drug test results due to the higher cutoff level in the final rule: 75 percent.[8]

- Changing the cutoff thresholds for marijuana and opiates will not result in a change in assay costs and will not require upgrading testing facility equipment because HHS-certified laboratories currently conduct testing to the cut-off levels for DOT regulated entities covered by 49 CFR Part 40.

- Percentage of confirmed positive drug test results appealed by some donors: 1 percent.

- Average amount of FFD manager time per appeal of a confirmed positive drug test result: 12.5 hours.

- Average amount of worker time per appeal of a confirmed positive drug test result: 2.0 hours.

Subparagraph 26.163(a)(2)

This subparagraph establishes that a licensee or other entity may require the HHS-certified laboratory to conduct special analyses on dilute specimens. The subparagraph states that if the initial validity test result of a urine specimen is dilute, the licensee or other entity has the option to require the laboratory to compare the quantitative test results for each drug tested to the cutoff calibrator in each drug class. If the initial test result for any drug is equal to or greater than 50 percent of the cutoff, the laboratory must conduct confirmatory testing to the LOD for the drug(s) and/or drug metabolites. These incremental costs are estimated and discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.163(b)

This paragraph revises former requirements in Section 2.7(f)(2) in Appendix A to Part 26, which pertained to the cutoff levels for confirmatory drug testing. The final rule will increase the cutoff levels used in confirmatory tests for morphine and codeine from 300 ng/mL to 2,000 ng/mL. The final paragraph will also establish a cutoff level of 10 ng/mL for 6-acetylmorphine, which is to be evaluated for specimens in which morphine is detected at or above the 2,000 ng/mL cutoff level. The incremental costs of the final rule changes are estimated and discussed in connection with §§ 26.133 and 26.163(a)(1) and include additional confirmed positive marijuana drug test results and fewer positive opiate drug test results.

[8]Relaxing the initial cutoff level for opiate metabolites will almost entirely eliminate the false positive issue associated with consuming poppy seeds and, unless an individual consumes large prescribed doses of codeine-based cough syrup or other cold prescriptions, the threshold will significantly reduce the number of tests that screen positive for opiates as a result of legitimate use of prescribed cold and cough prescriptions.

26.165 Testing split specimens and retesting single specimens

Paragraph 26.165(a)

This paragraph of the final rule imposes no incremental cost and affords no saving because it merely restates without substantive change former requirements in Section 2.7(j) in Appendix A to Part 26, which pertain to the split specimen testing procedures for Bottles A and B of a urine specimen, based on whether the licensee testing facility or HHS-certified laboratory analyzed the specimen in Bottle A.

Paragraph 26.165(b)

This paragraph of the final rule establishes a new provisions that permits a donor from an FFD program that does not follow split specimen collection procedures to request (through the MRO) a retest of an aliquot of a single specimen with a confirmed positive, adulterated, or substituted test result (provided the specimen quantity is 30 mL or more and the specimen is not invalid). This paragraph also restates former requirements in Section 2.7(j) in Appendix A to Part 26, which permitted testing of a split specimen with a confirmed positive drug test result for the initial specimen tested. The final rule adds a provision to permit split specimen testing for confirmed adulterated and substituted validity test results. The incremental costs associated with retesting split specimens with confirmed positive, adulterated, or substituted test results are estimated in connection with §§ 26.131 and 26.161(b)(1)-(5).

Incremental costs associated with a retest of an aliquot of a single specimen with a confirmed positive, adulterated, or substituted test result includes an increased number of retests for FFD programs that currently use single specimen collections, given that donors do not currently have the option to request a retest. The incremental costs estimated in this section account only for the retesting of an aliquot of a single specimen that returns a confirmed positive drug test result. The incremental costs calculated here do not include those associated with retesting an aliquot of a single specimen with confirmed adulterated or substituted validity test result, which are estimated separately in connection with §§ 26.131 and § 26.161(b)(1)-(5). Similarly, changes in cutoff levels for marijuana and opiates are estimated in connection with §§ 26.133, and 26.163(a)(1).

The *annual incremental cost per FFD program* is estimated as follows:

$$(NUM_{confirmed} \times PER_{retest} \times PERI_{retest} \times COST_{retest}) \times NUM_{reactors}$$

Parameter	Description
$NUM_{confirmed}$	Number of positive drug test results per reactor per year (as discussed in Appendix 2, Exhibit A2-12)
PER_{retest}	Percentage of urine specimens with positive drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below)
$PERI_{retest}$	Percentage increase in retesting of positive urine specimens based on the final rule provision to allow retesting of single specimens (as discussed in the assumptions below)

Parameter	Description
$COST_{retest}$	Cost of specimen retesting at a second HHS-certified laboratory including, specimen preparation and shipping costs (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{reactors}$	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Percentage of urine specimens with positive drug test results retested at the request of the donor at a second HHS-certified laboratory (as discussed in the assumptions below): 5 percent.

- Percent increase in retesting of positive drug test specimens based on the final rule provision to allow retesting of single specimens: 10 percent.

Paragraph 26.165(c)

This paragraph of the final rule revises former requirements in Section 2.7(i) and (j) in Appendix A to Part 26, which pertained to the procedures for testing split specimens for drugs at a second HHS-certified laboratory. The final rule adds procedures for retesting single specimens. The retesting of a urine specimen must be confirmatory testing for drugs and drug metabolites only for the drugs(s) that the specimen tested positive at the first HHS-certified laboratory. If the second HHS-certified laboratory fails to reconfirm the presence of the drug(s) detected at the initial HHS-certified laboratory, the second HHS-certified laboratory shall conduct specimen validity testing. The incremental costs for retesting single specimens is calculated and discussed in connection with § 26.165(b).

Paragraph 26.165(d)

This paragraph of the final rule establishes procedures for retesting urine specimens with confirmatory validity test results of adulterated at a second HHS-certified laboratory. Retesting of adulterated urine specimens is limited to conducting confirmatory testing only for the adulterant(s) identified by the first HHS-certified laboratory. The incremental costs associated with retesting urine specimens for adulterants are estimated and discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.165(e)

This paragraph of the final rule establishes procedures for retesting urine specimens with confirmatory validity test results of substituted at a second HHS-certified laboratory. Retesting of substituted urine specimens is limited to conducting confirmatory testing only for creatinine and specific gravity. The incremental costs associated with retesting urine specimens for substitution are estimated and discussed in connection with §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.165(f)

This paragraph of the final rule establishes FFD management actions and sanctions pertaining to situations where a donor has a confirmed positive, adulterated, or substituted drug and/or validity test result and requests the retesting of their specimen at a second HHS-certified laboratory. If the results of the retest do not confirm the initial result, that is, the second test indicates a negative drug and/or validity test result, this paragraph specifies procedures that the licensee and other entities must follow. The procedures and actions include not imposing any sanctions on the individual; eliminating any records from the individual's personnel files pertaining to the temporary administrative actions; prohibiting the disclosure of temporary administrative action in response to a suitable inquiry, a background investigation, or any other inquiry or investigation; and providing a written statement to the individual that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information. The analysis does not estimate the costs of the administrative actions (FFD program management labor to discard records and draft a written statement) associated with this final paragraph due to the infrequency of instances where the retesting of a positive, adulterated, or substituted validity and/or drug test specimen at a second HHS-certified laboratory fails to confirm the initial HHS-certified laboratory positive, adulterated, or substituted test result.

26.167 Quality assurance and quality control

Paragraph 26.167(a)

This paragraph of the final rule clarifies former requirements in Section 2.8(a) and (d) in Appendix A to Part 26, which specified that HHS-certified laboratories must implement a quality assurance program that encompasses all aspects of the testing process. The final rule adds a new requirement for the quality assurance program to encompass the certification of calibrators and controls to ensure that calibrators and controls are accurate. This paragraph in the final rule imposes no incremental costs and afford no savings because the requirements are consistent with the existing quality assurance programs implemented by HHS-certified laboratories.

Paragraph 26.167(b)

This paragraph of the final rule revises former requirements in Sections 2.8(c) and (d) in Appendix A to Part 26, which required HHS-certified laboratories to include appropriate calibrators and controls in each analytical run of initial and confirmatory drug test specimens. The final paragraph adds the requirement that appropriate calibrators and controls must be included in each analytical run for initial and confirmatory validity test specimens. The incremental costs resulting from validity testing are discussed in connection with § 26.161. This paragraph in the final rule imposes no incremental costs and afford no savings for drug testing because the requirements are consistent with the existing quality assurance programs implemented by HHS-certified laboratories

Paragraph 26.167(c)

This paragraph establishes quality control requirements for conducting initial and confirmatory

validity tests at HHS-certified laboratories. This final paragraph will impose incremental costs per FFD program on a per specimen test basis. That is, the per test cost to conduct validity testing includes the costs to comply with the quality control requirements in this paragraph. The incremental cost for FFD programs to conduct validity testing is calculated in §§ 26.131 and 26.161(b)(1)-(5).

Paragraph 26.167(d)

This paragraph of the final rule revises former requirements in Section 2.7(e)(1) in Appendix A to Part 26, which mandated that initial drug tests must be performed using an immunoassay that meets the FDA requirements for commercial distribution. The final rule prohibits the use of non-instrumented immunoassay testing devices pending HHS/SAMHSA review and approval from being used for initial drug testing under this part. The final rule also revises former requirements in Section 2.8(c) in Appendix A to Part 26, which pertained to the quality control requirements for performing initial drug tests at HHS-certified laboratories. This final paragraph imposes no incremental costs and affords no savings because the provisions are consistent with the existing practices of HHS-certified laboratories.

Paragraph 26.167(e)

This paragraph of the final rule revises former requirements in Sections 2.7(f)(2) and 2.8(d) in Appendix A to Part 26, which pertained to quality control requirements for performing confirmatory drug tests at HHS-certified laboratories. This final paragraph imposes no incremental costs and affords no savings because the provisions are consistent with existing practices of HHS-certified laboratories.

Paragraph 26.167(f)

This paragraph of the final rule clarifies former requirements in Sections 2.8(e)(4)–(6) in Appendix A to Part 26, which pertained to errors in HHS-certified laboratory testing of blind performance test specimens and actual specimens, as well as errors identified through processing reviews and any matters that may adversely affect the testing process. The final paragraph requires licensees and C/Vs to ensure that the HHS-certified laboratory conducts investigations into any testing errors and takes corrective action when necessary. The final paragraph will impose no incremental costs and affords no savings because the requirement is consistent with current quality assurance procedures used by HHS-certified laboratories.

Paragraph 26.167(g)

This paragraph of the final rule imposes no cost and affords no savings because it restates former requirements in Section 2.7(o)(3)(i) in Appendix A to Part 26.

Paragraph 26.167(h)

This paragraph of the final rule revises without substantive change the former requirements in

Section 2.7(o)(2) in Appendix A to Part 26 which described the preparation and handling procedures for standards and controls. This paragraph clarifies that HHS-certified laboratories may prepare calibrators and controls from stock solutions obtained from other laboratories or commercial manufacturers. This final paragraph also adds a provision that prohibits HHS-certified laboratories from using calibrators and controls prepared from the same stock solution. No incremental cost or saving will result from the provisions in this paragraph because they are consistent with existing laboratory practices pertaining to calibrator and control preparation.

26.168 Blind Performance Testing

Paragraph 26.168(a)

This paragraph of the final rule revises former requirements in Section 2.8(e)(2)–(3) in Appendix A to Part 26, which pertained to blind performance test samples. This revision will result in incremental savings for each FFD program, as discussed in connection with § 26.168(a)(1)–(2).

Subparagraph 26.168(a)(1)

This subparagraph in the final rule revises former requirements in Section 2.8(e)(2) in Appendix A to Part 26, which pertained to the number of blind performance test samples that licensees and other entities were required to submit to an HHS-certified laboratory during the initial 90 days of any contract (not including rewritten or renewed contracts). Under the former requirements, during the initial 90 days of a contract, 50 percent of the total number of specimens submitted were required to be blind performance test samples (up to a maximum of 500 samples). The final rule reduces the number of blind performance test samples that must be submitted by a licensee or other entity in the initial 90 days of a contract to 20 percent (up to a maximum of 100 blind samples) or 30 blind samples, whichever is greater. The final rule will result in incremental savings for some FFD programs and costs for other FFD programs, as follows:

- FFD programs that conduct all testing at HHS-certified laboratories ("offsite laboratories") will recognize savings related to the reduced number of blind performance test samples purchased from commercial vendors and analyzed at HHS-certified laboratories.

- In contrast, FFD programs that conduct initial validity and drug testing of specimens at onsite licensee testing facilities send HHS-certified laboratories many fewer urine specimens for testing under the former rule requirements.[9] Unlike the former rule, the final rule requires an FFD program to submit a minimum number of blind performance test samples to their HHS-certified laboratory. Therefore, this provision increases the number of blind samples that FFD programs with onsite licensee testing facilities must submit to HHS-certified laboratories. For this reason, FFD programs using onsite licensee testing

[9]Specifically, FFD programs with onsite licensee testing facilities submit to HHS-certified laboratories only positive initial drug test specimens, and a "sampling" of negative urine specimens (assumed to be 1 percent) analyzed at the licensee testing facility.

facilities will incur incremental costs for an increased number of blind samples purchased from commercial vendors and analyzed at HHS-certified laboratories.

Annual saving per FFD program that uses an HHS-certified laboratory for all validity and drug testing of urine specimens is calculated as the difference between the costs under the former rule and costs under the final rule, as follows:

$$[(NUM_{\text{drug tests per quarter}} \times PER_{\text{blind samples, initial 90 days, former rule}} \times COST_{\text{blind sample and testing, former rule}} \times NUM_{\text{reactors}}) - (NUM_{\text{drug tests per quarter}} \times PER_{\text{blind samples, initial 90 days, final rule}} \times COST_{\text{blind sample and testing, final rule}} \times NUM_{\text{reactors}})] \times PER_{\text{change HHS lab}}$$

Annual cost per FFD program that conducts initial validity and drug testing of specimens at an onsite licensee testing facility is calculated as the difference between the costs under the former rule and costs under the final rule, as follows:

$$[(NUM_{\text{specimens to HHS lab per quarter from LTF}} \times PER_{\text{blind samples, initial 90 days, former rule}} \times COST_{\text{blind sample and testing, former rule}} \times NUM_{\text{reactors}}) - (NUM_{\text{specimens to HHS per quarter from LTF}} \times PER_{\text{blind samples, initial 90 days, final rule}} \times COST_{\text{blind sample and testing, final rule}} \times NUM_{\text{reactors}})] \times PER_{\text{change HHS lab}}$$

Parameter	**Description**
$NUM_{\text{drug tests per quarter}}$	Number of drug tests per reactor per quarter (as discussed in the assumptions below and in Appendix 2, Exhibit A2-14)
$PER_{\text{blind samples, initial 90 days, former rule}}$	Percentage of drug test specimens under the former rule that must be blind performance test samples submitted in the first 90 days of a contract with an HHS-certified laboratory (as discussed in the assumptions below)
$COST_{\text{blind sample and testing, former rule}}$	Cost per blind specimen under the former rule for an FFD program to purchase a blind performance test sample from a commercial vendor, prepare the sample (fill out custody-and-control form, submit the sample for testing to an HHS-certified laboratory, drug test the specimen, and labor to verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$PER_{\text{blind samples, initial 90 days, final rule}}$	Percentage of drug test specimens under the final rule that must be blind performance test samples submitted in the first 90 days of a contract with an HHS-certified laboratory (as discussed in the assumptions below)
$COST_{\text{blind sample and testing, final rule}}$	Cost under the final rule provisions for an FFD program to purchase a blind performance test sample from a commercial vendor, prepare the sample (fill out custody-and-control form), submit the sample for testing to an HHS-certified laboratory, drug and validity test the specimen, and labor to verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$PER_{\text{change HHS lab}}$	Percentage of years that an FFD program enters a contract with a different HHS-certified laboratory (as discussed in the assumptions below)
$NUM_{\text{specimens to HHS lab per quarter from LTF}}$	Number of urine specimens per reactor per quarter submitted to an HHS-certified laboratory by FFD programs that conduct initial specimen testing at an onsite licensee testing facility (LTF) (as discussed in the assumptions below and in Appendix 2, Exhibit A2-12)
NUM_{reactors}	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- The number of drug tests conducted per reactor per quarter is equivalent to the number of drug tests per conducted per reactor per year (see Appendix 2, Exhibit A2-14) divided by 4 quarters in the year.

- Percentage of years that a FFD program enters a contract with a different HHS-certified laboratory: 10 percent. That is, on average, a FFD program will choose to use a different HHS-certified laboratory every 10 years.

- Percentage price increase per blind performance test sample purchased from a commercial vendor under the final rule due to the inclusion of adulterated, substituted, and dilute validity test specimens as well as samples submitted as a false negative challenge §§ 26.168(a)(3)–(a)(6): 75 percent.

- The number of urine specimens per reactor per quarter submitted to an HHS-certified laboratory by FFD programs that conduct initial specimen testing at an onsite licensee testing facility (LTF) is equal to the total per quarter of the following:

    - positive initial drug test specimens, and

    - a "sampling" of negative urine specimens [assumed to be 1 one percent] as a check on false negative rate

Subparagraph 26.168(a)(2)

This subparagraph of the final rule revises former requirements in Section 2.8(e)(2) in Appendix A to Part 26, which pertained to the number of blind performance test specimens that licensees and C/Vs must submit to their HHS-certified laboratory during each quarter after the initial 90 days of the contract with the laboratory. Under the former regulations, 10 percent of the total number of samples submitted per quarter (up to a maximum of 250 samples) had to be blind performance test specimens. Th final rule reduces that number to a minimum of 1 percent of the total number of samples submitted per quarter (up to a maximum of 100 samples) or 10 blind specimens, whichever is greater. This subparagraph in the final rule will result in incremental savings for some FFD programs and costs for other FFD programs, as follows:

- FFD programs that send all urine specimens to HHS-certified laboratories ("offsite laboratories") will recognize incremental savings related to the reduced number of blind performance test specimens purchased from commercial vendors and validity and drug tested at HHS-certified laboratories.

- In contrast, FFD programs that conduct testing at onsite licensee testing facilities send

HHS-certified laboratories many fewer specimens for testing under the former rule.[10] Unlike the former rule, the final rule requires licensees testing facilities to submit a minimum number of blind performance test samples to their HHS-certified laboratories. Therefore, the final rule increases the number of blind specimens that onsite licensee testing facilities must submit to HHS-certified laboratories. For this reason, FFD programs that conduct testing of urine specimens at onsite licensee testing facilities will incur incremental costs for an increased number of blind performance test samples purchased from commercial vendors and submitted to HHS-certified laboratories for drug and validity testing.

Annual saving per FFD program that uses an HHS-certified laboratory to conduct all urine specimen testing. The saving per FFD program with a contract with an HHS-certified laboratory that has been in place for more than 90 days is calculated as the difference between the costs under the former rule and the costs after implementation of the final rule, as follows:

$$(NUM_{\text{drug tests per quarter}} \times PER_{\text{blind specimens, former rule}} \times COST_{\text{blind specimen testing, former rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}}) - (NUM_{\text{drug tests per quarter}} \times PER_{\text{blind specimens, final rule}} \times COST_{\text{blind specimen testing, final rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}})$$

Annual cost per FFD program that conducts testing of urine specimens at a licensee testing facility (LTF) is calculated as the difference between the costs under the former rule and costs after implementation of the final rule, as follows:

$$(NUM_{\text{drug tests to HHS lab per quarter, LTF}} \times PER_{\text{blind specimens, former rule}} \times COST_{\text{blind specimen testing, former rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}}) - (NUM_{\text{drug tests to HHS lab per quarter, LTF}} \times PER_{\text{blind specimens, final rule}} \times COST_{\text{blind specimen testing, final rule}} \times NUM_{\text{reactors}} \times NUM_{\text{quarters in year}})$$

Parameter	**Description**
$NUM_{\text{drug tests per quarter}}$	Number of drug tests per reactor per quarter (as discussed in the assumptions below)
$PER_{\text{blind specimens, former rule}}$	Percentage of drug tests under the former rule that must be blind performance test specimens submitted during each quarter for a contract with an HHS-certified laboratory that has been in place for more than 90 days (as discussed in the assumptions below)
$COST_{\text{blind specimen testing, former rule}}$	Cost per blind specimen under the former rule for an FFD program to purchase a blind performance test specimen from a commercial vendor, prepare the specimen for testing (fill out custody-and-control form), submit the specimen for testing at the HHS-certified laboratory, and verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$PER_{\text{blind specimens, final rule}}$	Percentage of drug tests under the final rule that must be blind performance test specimens submitted during each quarter for a contract with an HHS-certified laboratory that has been in place for more than 90 days (as discussed in the assumptions below)

[10]Specifically, FFD programs with onsite licensee testing facilities submitted to HHS-certified laboratories only positive initial drug test specimens, and a "sampling" of negative urine specimens [assumed one percent].

Parameter	Description
$COST_{\text{blind specimen testing, final rule}}$	Cost per blind specimen under the former rule for an FFD program to purchase a blind performance test specimen from a commercial vendor, prepare the specimen for testing (fill out custody-and-control form), submit the specimen for testing at the HHS-certified laboratory, and verify that the test results are accurate (as discussed in Appendix 2, Exhibit A2-13)
$NUM_{\text{drug tests to HHS lab per quarter, LTF}}$	Number of drug tests submitted to an HHS-certified laboratory per reactor per quarter for licensees that conduct testing of urine specimens at onsite licensee testing facilities (LTF) (as discussed in the assumptions below)
$NUM_{\text{quarters in year}}$	Number of quarters in a year (as discussed in the assumptions below)
NUM_{reactors}	Number of reactors per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- The number of drug tests per reactor per quarter is equivalent to the number of drug tests per reactor per year (see Appendix 2, Exhibit A2-14) divided by the number of quarters in a year.

- The number of quarters in a year:[11] 4.

- The number of specimens per reactor per quarter submitted to an HHS-certified laboratory from FFD programs with onsite licensee testing facilities (LTF) is equal to the total per quarter of:

    - positive initial drug test specimens, and

    - a "sampling" of negative urine specimens [assumed to be 1 one percent] as a check on the false negative rate

- Percentage price increase per blind performance test sample purchased from a commercial vendors under the final rule due to the inclusion of adulterated, substituted, dilute samples, as well as "false negative challenge" samples as required by §§ 26.168(d) and (e): 75 percent.

Paragraph 26.168(b)

[11]The § 26.168(a)(2) equations for FFD programs that have onsite licensee testing facilities and those that send all specimens to an HHS-certified laboratory for testing both account for four quarters of blind specimen testing costs. For the ten percent of FFD programs accounted for in § 26.168(a)(1) that switch to new HHS-certified laboratories, this means that there is one quarter of over counting of costs/savings under § 26.168(a)(2). Consequently, the equations in § 26.168(a)(2) somewhat overstate the savings/costs for those FFD programs accounted for in § 26.168(a)(1). The net overstatement is small, however, and does not merit the complication that would be needed to provide a more precise estimate.

This paragraph in the final rule revises the former requirements in Section 2.8(e)(3) in Appendix A to Part 26, which specified the percentage of positive blind specimens that licensees and other entities had to submit to their HHS-certified laboratories. Under the former regulations, 20 percent of the total number of blind performance test specimens submitted per quarter had to be positive for one or more drugs. The final rule increases the percentage of blind performance test samples positive for one or more drugs or drug metabolites that must be submitted to HHS-certified laboratories to 60 percent. The provision changes the "mix" or composition of blind performance test samples that FFD programs must submit for testing and will result in an incremental cost per program associated with the composition change in the blind performance test samples is accounted for in connection with §§ 26.168(a)(1)–(a)(2).

Paragraph 26.168(c)

This paragraph in the final rule establishes a requirement that licensee and other entities may only submit blind performance test samples positive for only the drugs that the FFD program tests the presence for in each specimen. No incremental cost or saving will result from the final provision because the requirement simple ensures that the licensee and other entity is measuring the ability of the HHS-certified laboratory to detect drugs that the FFD program is testing for in each specimen.

Paragraph 26.168(d)

This paragraph of the final rule establishes a new requirement that licensees and other entities submit approximately 10 percent of all blind performance test samples as false negative challenge samples to the HHS-certified laboratory according to the requirements established in § 26.168(g)(3). This provision will result in incremental costs associated with purchasing false negative challenge samples and submitting the samples for testing. These incremental costs are accounted for in connection with § 26.168(a)(1) and (2).

Paragraph 26.168(e)

This paragraph of the final rule establishes a new requirement that licensees and other entities must submit approximately 20 percent of all blind samples as adulterated, diluted, or substituted specimens. This paragraph will result in incremental costs associated with purchasing adulterated, substituted, and dilute samples meeting the requirements in § 26.168(g)(4) - (g)(6) and submitting the samples for testing. These incremental costs are accounted for in connection with § 26.168(a)(1) and (2).

Paragraph 26.168(f)

This paragraph in the final rule revises the former requirements in Section 2.8(e)(3) in Appendix A to Part 26, which specified the percentage of negative blind specimens that licensees and other entities had to submit to their HHS-certified laboratories. Under the former regulations, 80 percent of the total number of blind specimens submitted per quarter had to be "blank." Licensees will realize an incremental increase in costs associated with the increased number of

more costly adulterated, diluted, substituted and false negative challenge blind performance test samples required in § 26.168(d) and (e) of the final rule. These incremental costs are accounted for in connection with §§ 26.168(a)(1)–(2).

Paragraph 26.168(g)

This paragraph specifies the criteria that each type of blind performance test specimens must meet. This paragraph specifies that blind performance test samples must be certified by the supplier to be negative (i.e., certified by immunoassay and confirmatory testing as containing no drug), drug positive (i.e., certified by immunoassay and confirmatory testing as containing one or more drug(s)/and/or metabolite(s)), adulterated (i.e., certified using one or more appropriate analytical procedure(s)) as being adulterated with a specific adulterant), substituted (i.e., certified as having a creatinine concentration and a specific gravity that satisfy the criteria for a substituted specimen) or a false negative challenge. The provisions in this paragraph will result in incremental costs for FFD programs to purchase blind performance test samples that meet the specifications of the final rule, as discussed in connection with § 26.168(a)(1) and (a)(2).

Paragraph 26.168(h)

Paragraph 26.168(h) establishes requirements for blind performance test samples that licensees and other entities must submit to the HHS-certified laboratories to ensure to the consistency and effectiveness of the blind performance testing process. The paragraph requires the supplier of the blind samples to: (1) certify that all blind specimen lots are confirmed by an HHS-certified laboratory prior to being put into service, (2) provide an expiration date for each sample, and (3) to monitor each open lot on a bi-monthly (i.e., every two month) basis to ensure that samples remaining in the lot do not fall below the criteria in this section. Although these provisions may be normal industry practice for some manufacturers, the analysis accounts for an incremental cost that may result for some manufacturers that would pass the additional cost to the licensee or other entity in terms of higher blind sample costs. The costs associated with these provisions are accounted for in the increased cost to purchase a blind performance test sample under the final provisions in § 26.168(a)(1) and (2).

Paragraph 26.168(i)

This paragraph of the final rule establishes the procedures that a licensees and other entities must follow to ensure that each blind performance test sample that is sent to an HHS-certified laboratory for testing is indistinguishable from a donor specimen sent to a laboratory. The paragraph requires that the blind performance test samples be sent from the same channels that donor specimens are sent to the laboratory (e.g., from the collection site, licensee testing facility). The paragraph also requires that if split specimen collection is performed, the tamper-evident bottle seals must be initialed and the collector must inform the MRO on the MRO copy of the custody and control form that the sample is a blind performance test sample. Finally, the paragraph requires that if a licensee or other entity uses split specimen collections for donors, the blind performance test sample must also be a split specimen sample. No incremental cost or saving will result from the provisions in this paragraph because they are consistent with existing

blind performance test sample preparation.

26.169 Reporting results

Paragraph 26.169(a)

This paragraph of the final rule revises former requirements in Section 2.7(g)(1) in Appendix A to Part 26, which pertained to HHS-certified laboratories reporting drug test results to MROs. The final rule will add a requirement that the laboratory's reports must include validity testing results and any indications of tampering, adulteration, or substitution. The final paragraph will impose no incremental costs and affords no savings because HHS-certified laboratories already conduct validity testing for some U.S. DOT-regulated entities and, therefore, have the capability to report validity testing results, using existing automated systems.

Paragraph 26.169(b)

This paragraph of the final rule revises former requirements in Section 2.7(g)(7) in Appendix A to Part 26, which pertained to HHS-certified laboratories reporting test results for licensees who use cutoff levels that are more stringent than those required in Part 26. Currently, HHS-certified laboratories must report drug test results for both the Part 26 cutoff levels, and the licensee's more stringent cutoff levels. By contrast, under the final rule HHS-certified laboratories are only required to report the results for the more stringent cutoff levels. Given that HHS-certified laboratories use automated systems to tabulate testing data, printing fewer data items for the test results is unlikely to result in any incremental costs or savings to either FFD programs or HHS-certified laboratories.

Paragraph 26.169(c)

This paragraph of the final rule clarifies and amends former requirements in Section 2.7(g)(2) in Appendix A to Part 26, which pertained to HHS-certified laboratories reporting negative and positive, adulterated, substituted, dilute, and invalid test results. The final rule also establishes that HHS certified laboratories must report negative, positive, adulterated, substituted, dilute, and invalid test results. The final paragraph will impose no incremental costs and affords no savings because HHS-certified laboratories already conduct validity testing for U.S. DOT-regulated entities and, therefore, have the capability to report validity testing results, using existing automated systems.

Paragraph 26.169(e)

This paragraph of the final rule imposes no incremental cost and affords no saving because it restates former requirements within Section 2.7(g)(4) in Appendix A to Part 26 pertaining to the acceptable transmission methods to send test results from the HHS-certified laboratory to the MRO. This final paragraph also revises a former requirement in Section 2.7(g)(4) in Appendix A to Part 26 which required the HHS-certified laboratory to ensure that security of data transmission, data access, storage, and retrieval systems. This final paragraph clarifies that the

licensee or other entity, directly or through the HHS-certified laboratory, must ensure the security of data transmission, data storage, and data retrieval systems. Under the former rule the licensee or other entity is still ultimately responsible for the compliance of the HHS-certified laboratory (given licensee and other entity oversight requirements) even though the text in Section 2.7(g)(4) did not clearly specify this responsibility. This revision will result in no increment cost or savings because it is consistent with existing licensee and other entity data security evaluation procedures.

Paragraph 26.169(f)

This paragraph of the final rule revises former requirements in Section 2.7(g)(5) in Appendix A to Part 26, which pertained to acceptable methods for HHS-certified laboratories to use in transmitting the custody-and-control form to the MRO. Currently, HHS-certified laboratories are required to transmit a certified copy of the original custody-and-control form with a copy of the test report. The final paragraph expands the acceptable methods of transmitting the custody-and-control form to include fax, courier, mail, and electronic transmission. Although this final paragraph provides flexibility in the transmission mechanism, it will result in insignificant incremental costs or savings.

Paragraph 26.169(g)

This paragraph of the final rule clarifies that the HHS-certified laboratory must retain the original custody-and-control form for any specimen with a positive, adulterated, substituted, dilute, or invalid result and transmit to the MRO a copy of the original custody-and-control form signed by the certifying scientist. No incremental costs or savings will result from the final paragraph as it is consistent with existing HHS-certified laboratory recordkeeping practices.

Paragraph 26.169(h)

This paragraph of the final rule revises and amends former requirements in Sections 2.7(g)(6) and (g)(7) in Appendix A to Part 26, which required HHS-certified laboratories to prepare statistical summary reports of each licensee's drug test results, and submit those reports to the licensee official on a monthly basis. By contrast, the final paragraph will reduce the reporting frequency from monthly to annually thereby providing more flexibility in the reporting of this data. However, the final rule includes a new reporting requirement in the summary reports to include validity testing results (i.e., information on specimens with adulterated, substituted, diluted, or invalid test results). No incremental costs are expected to result from the requirement to include validity test summary data, because HHS-certified laboratories already have the data management systems to provide summary test result information. However, this final paragraph will yield incremental savings by reducing the required frequency of statistical summary reports (i.e., reduced labor and postage costs).

The *annual saving per FFD program* is estimated as follows:[12]

[12] In order to capture total costs and savings, the analysis assumes that savings recognized by HHS-certified laboratories will be passed back to licensees (i.e., lower specimen testing costs).

$[(HOURS_{lab\ tech} \times WAGE_{lab\ tech}) + COST_{postage}] \times NUM_{reports} \times NUM_{facility}$

Parameter	Description
$HOURS_{lab\ tech}$	Time for the laboratory technician to generate and send an annual or monthly statistical summary report per facility (as discussed in the assumptions below)
$WAGE_{lab\ tech}$	Laboratory technician wage rate (as discussed in Appendix 2, Exhibit A2-11)
$COST_{postage}$	Cost to send an annual or monthly statistical summary report via the U.S. Postal Service (as discussed in the assumptions below)
$NUM_{reports}$	Number of reports that will no longer be sent to a facility per year (as discussed in the assumptions below)
$NUM_{facilities}$	Number of facilities per FFD program (as discussed in Appendix 2, Exhibit A2-14)

Assumptions:

- Time for the laboratory technician to generate an send annual or monthly statistical summary report per facility: 30 minutes.
- Cost to send an annual or monthly statistical summary report via the U.S. Postal Service: $2.00.
- Number of reports that will no longer be sent to a facility per year: 11.
- An annual summary report requires the same amount of labor and postage as a monthly summary report.