placing a competitive bid for that account either in the name of the investment adviser or in the name of the account. However, if any net long position less than $100 million of any nonproprietary account not being bid for is excluded, then all net short positions less than $100 million of nonproprietary accounts not being bid for must also be excluded. Regardless of whether the investment adviser bids in its own name or in the name of its controlled accounts, if the net long position is reportable, it must be reported as a total in connection with only one bid in accordance with § 356.13(a).

(d) *Submitting bids for controlled accounts.* Notwithstanding the definition of submitter found in § 356.2, and the restriction against submitting bids for others found in § 356.14, an investment adviser may submit bids, whether in the adviser's own name or in the names of its controlled accounts, directly to a Federal Reserve Bank or the Bureau of the Public Debt, in which case the investment adviser is considered a submitter. In the alternative, the investment adviser may forward such bids to a depository institution or dealer.

(e) *Certifications.* By bidding for a controlled account, an investment adviser is deemed to have certified that it is in compliance with this part and the offering announcement governing the sale and issue of the security. Further, the investment adviser is deemed to have certified that the information provided on the tender or provided to a submitter or intermediary with regard to bids for controlled accounts is accurate and complete.

(f) *Proration of awards.* In auctions where bids at the highest accepted yield or discount rate are prorated under § 356.20(a)(2) of this part, investment advisers that submit bids for controlled accounts in the names of such accounts are responsible for prorating awards for their controlled accounts at the same percentage as that announced by the Department. The same prorating rules apply to controlled accounts as apply to submitters. See § 356.21 of this part.

6. Section 356.21 is amended by revising paragraph (a) to read as follows:

§ 356.21 Proration of awards.

(a) *Awards to submitters.* In auctions where bids at the highest accepted yield or discount rate are prorated under § 356.20(a)(2) of this part, the Federal Reserve Banks are responsible for prorating awards for submitters at the percentage announced by the Department. For example, if 80% is the announced percentage at the highest yield or discount rate, then each bid at that rate or yield shall be awarded 80% of the amount bid. Hence, a bid for $100,000 at the highest accepted yield or discount rate would be awarded $80,000. In all cases, awards will be for, at least, the minimum to hold, and awards must be in an appropriate multiple to hold. Awards at the highest accepted yield or rate are adjusted upwards, if necessary, to an appropriate multiple to hold. For example, Treasury bills may be issued with a minimum to hold of $10,000 and multiples of $1,000. Where an $18,000 bid is accepted at the high discount rate, and the percent awarded at the high discount rate was 88%, the award to that bidder would be $16,000, representing an upward adjustment from $15,840 ($18,000 × .88) to an appropriate multiple to hold. If tenders at the highest accepted rate were prorated at, for example, a rate of 4%, the award for a $100,000 bid would be $10,000, instead of $4,000, in order to meet the minimum to hold for a bill issue.

* * * * *

7. Section 356.22(b) is amended by revising the last sentence to read as follows:

§ 356.22 Limitation on auction awards.

* * * * *

(b) *Awards to competitive bidders.* * * * When the bids and net long positions of more than one person or entity must be combined as required by § 356.15(c), such combined amount will be used for the purpose of this award limitation.

8. Section 356.36 is revised to read as follows:

§ 356.36 Paperwork Reduction Act approval.

The collections of information contained in §§ 356.11, 356.12, 356.13, 356.14, and 356.15 and in appendix A of this part have been approved by the Office of Management and Budget under control number 1535–0112.

9. Appendix A to Part 356 is amended by adding to section (a) a new paragraph between the second and third paragraphs of the introductory text to read as follows:

Appendix A To Part 356—Bidder Definitions

* * * * *

(a) *Corporation*—* * *

For the purpose of this part, a business trust, such as a Massachusetts business trust or a Delaware business trust, is considered to be a corporation.

* * * * *

Dated: July 9, 1996.

John A. Kilcoyne,

Acting Fiscal Assistant Secretary.

[FR Doc. 96–17896 Filed 7–15–96; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 413

[BPD–647–F]

RIN 0938–AH11

Medicare Program; Reporting of Interest From Zero Coupon Bonds

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule requires Medicare providers to report all interest expense and interest income from zero coupon bonds in the cost reporting period in which the interest was accrued. This final rule is necessary to add provisions to the Medicare regulations that specifically address the reporting by providers of interest expense and income from zero coupon bonds.

EFFECTIVE DATE: This regulation is effective on August 15, 1996.

FOR FURTHER INFORMATION CONTACT: Ann Pash, (410) 786–4615.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1861(v)(1)(A) of the Social Security Act (the Act) defines reasonable cost for any service under Medicare as the cost actually incurred, excluding any cost unnecessary in the efficient delivery of needed health services. That section of the Act also provides that reasonable costs must be determined in accordance with regulations that establish the methods to be used and the items to be included for purposes of determining which costs are allowable for various types or classes of institutions, agencies, and services. In addition, section 1861(v)(1)(A) of the Act specifies that regulations implementing the principles of reasonable cost payment may provide for the use of different methods in different circumstances. This section of the Act is implemented by regulations at 42 CFR part 413. In particular, § 413.24 establishes the methods to be used and the adequacy of data needed to determine allowable costs for various types or classes of institutions, agencies, and services.

Under Medicare, providers are paid for inpatient and outpatient services that they furnish to beneficiaries under Part A (Hospital Insurance) or Part B (Supplementary Medical Insurance). Currently, most hospitals are paid for their hospital inpatient operating costs and capital-related costs under the prospective payment systems in accordance with sections 1886 (d) and (g) of the Act and regulations at 42 CFR part 412. Under these systems, Medicare payment is made at a predetermined, specific rate for inpatient operating costs and inpatient capital-related costs for each hospital discharge based on the information contained in actual bills submitted. Section 1886(f)(1)(A) of the Act requires us to maintain a system for reporting costs of hospitals paid under the prospective payment systems. This provision is implemented by regulations at § 412.52. Section 412.52 requires all prospective payment system hospitals to meet the cost reporting requirements of §§ 413.20 and 413.24, which include submitting a cost report for each 12-month period.

Hospital outpatient units and hospitals and hospital units that are excluded from the prospective payment systems, as well as most other providers, are generally paid an amount based on the reasonable cost of items and services furnished to beneficiaries, in accordance with section 1861 (v)(1)(A) of the Act, the regulations at 42 CFR part 413, and the Provider Reimbursement Manual. These cost-based providers are subject to the same cost reporting requirements of §§ 413.20 and 413.24 and thus must maintain financial records and statistical data sufficient for the proper determination of costs payable under the Medicare program and submit cost reports on an annual basis.

For cost-based providers (and for prospective payment hospitals during the capital prospective payment system transition period), interest expense on capital indebtedness such as loans for acquiring facilities and equipment or for making capital improvements and on current indebtedness is an allowable cost as set forth at §§ 413.130(a)(7) and 413.153. Interest must be necessary—that is, incurred on a loan made to satisfy the financial need of a provider, and for a purpose reasonably related to patient care. It must also be proper—that is, incurred at a rate not in excess of that which a prudent borrower would have to pay in the money market when the loan was made.

One source of financing for providers is the sale of zero coupon bonds. Similarly, one source of provider investment income is the purchase of zero coupon bonds. The name ''zero coupon bond'' is derived from the fact that there are no coupons issued with these bonds. Zero coupon bonds are issued by government agencies, corporations (including Medicare providers), and banks at a price substantially below the face value of the bond. The difference between the purchase price of a zero coupon bond and the face amount payable at maturity reflects the actual amount of interest and is neither a discount nor an adjustment to the interest rate as with most other bonds. All interest is actually paid when the bond is presented for redemption, at face value, on the date of maturity.

II. Policy Changes

A. Interim Policy

As discussed in detail in our December 13, 1993 proposed rule (58 FR 65150), on December 22, 1989, we issued a Regional Office memorandum for distribution to all intermediaries that allowed providers to choose which method they would use to report interest expense or income from zero coupon bonds—either at maturity in a lump sum, or each year as the interest accrues, as long as their treatment of interest expense is consistent with their treatment of interest income.

We stated that this interim policy would apply to all zero coupon bonds issued or purchased on or after December 22, 1989, as well as to any zero coupon bond interest reported on cost reports that could be amended or reopened as of December 22, 1989. Thus, a provider's options under the interim policy are as follows:

- *Bonds Issued before December 22, 1989:* For interest from zero coupon bonds issued before December 22, 1989, that is reportable on cost reports that could be amended or reopened as of December 22, 1989, a provider could request amendment or reopening and specify the method to be used for reporting interest expense and income on zero coupon bonds. Conversely, by not requesting an amendment or reopening, a provider could choose to continue the method already in use.
- *Bonds Issued on or after December 22, 1989, and before February 22, 1991:* For all zero coupon bonds issued on or after December 22, 1989, but before February 22, 1991, a provider could choose the method it would use to report interest expense or income, as discussed above. Therefore, in cases where a provider's cost reports are not amended, or cost report determinations are not reopenable, on or after December 22, 1989, the provider's preference would be evidenced by the choice the provider exercises for the first zero coupon bonds issued or purchased on or after December 22, 1989, but before February 22, 1991. In either case, once the provider has exercised its choice, the method of reporting interest accrued on all zero coupon bonds issued or purchased from that date through February 21, 1991, should be consistent with that choice.

B. Current Policy (Applicable to Bonds Issued on or after February 22, 1991)

We revised the Medicare Provider Reimbursement Manual (Transmittal No. 358) in February 1991 to establish our current policy. In developing the manual issuance, we concluded that it was not appropriate to continue to permit the provider to report accrued interest in a lump sum at maturity because the interest accrues during the life of the bond. We now require that, for zero coupon bonds issued or purchased by providers on or after February 22, 1991, all interest expense and income must be reported in the cost reporting period in which the interest accrues.

Neither the policy enunciated in our December 22, 1989, Regional Office memorandum nor the one in the Provider Reimbursement Manual has been set forth in regulation.

III. Provisions of the Proposed Rule

On December 13, 1993, we published in the Federal Register (58 FR 65150) a proposed rule to add to the Medicare regulations at 42 CFR 413.153 provisions that specifically address the reporting by providers of interest expense and interest income from zero coupon bonds. We also proposed to add the definition of ''zero coupon bond'' to the regulations.

Under our proposal, for zero coupon bonds issued on or after the effective date of a final regulation, interest expense incurred to finance capital-related costs would be an allowable expense, and interest income earned for investment purposes would be an allowable offset, in the cost reporting period in which the interest accrues. We proposed that earned interest from zero coupon bonds must be offset against all allowable interest expense as set forth in § 413.130(g)(2). In addition, interest expense must meet the definition of ''necessary'' in § 413.153(b)(2)(iii).

For cost reporting purposes, we proposed to require the use of the effective interest method rather than the straight line method. Under the straight line method, the interest for a computation period is computed by dividing the total interest payable (the

value at maturity less the amount paid) by the number of compensation periods. This method recognizes the average interest expense or income for each compensation period.

Under the effective interest method, we indicated that in each computation period (as specified by the bond instrument) we would apply the interest rate to the sum of the face amount and the accrued interest from prior periods. If the interest computation period involves portions of more than one cost reporting period, the amount of interest for that computation period would be apportioned to each cost reporting period. This method recognizes the actual accrual of interest expense or income for each interest computation period (as specified by the bond instrument) throughout the life of the bond to maturity. A constant effective yield rate is determined and applied to the book value (outstanding loan balance including prior accrued interest) of the bond at the beginning of each period to determine the total interest for the period. We also proposed to set forth in the regulations under proposed § 413.153(f)(3)(iv) an example of the computation of interest using the effective interest method.

IV. Analysis of and Responses to Public Comments

We received two letters of comment on the December 22, 1993 proposed rule. These comments and our responses are discussed below.

Comment: One commenter questioned whether the effective date of the final regulation would be the February 22, 1991, effective date of the manual provisions. The commenter also wanted us to explain the current applicability of the interim policies in the Regional Office memorandum dated December 22, 1989, and in the Provider Reimbursement Manual for the interim period before the effective date of this final rule. The commenter stated that if the final rule has an effective date other than February 22, 1991, the manual provisions would be inconsistent with the regulation.

Response: This final rule is effective on August 15, 1996 and applies to bonds issued on and after that date. This date is not inconsistent with the effective dates of HCFA's prior policies addressing reimbursement for zero coupon bond interest. The reimbursement policies in existence before the effective date of this final rule apply to cost reporting periods that precede the promulgation of this final rule, and the policies continue in force only with respect to bonds issued before August 15, 1996. The December 22, 1989 memorandum provided that for interest from zero coupon bonds issued before December 22, 1989 (that is reportable on a cost report that can be reopened on or after December 22, 1989), a provider could request amendment or reopening to specify the method of reporting the interest expense and income on the zero coupon bonds.

The memorandum did not establish a time limitation on these requests. However, in order to effectuate an orderly implementation of this rule, we are requiring providers to submit requests for reopening or amendment within 60 days of publication of this final rule, that is by September 16, 1996. Any request received after that date will not be considered timely and will not be honored.

The provisions of this final rule supersede any agency policy that is inconsistent with the regulation's terms.

Comment: One commenter stated that while the preamble and the regulation text of the proposed rule referred to interest expense incurred to finance capital-related costs, section 213(A) of the Provider Reimbursement Manual refers to ''issuing zero coupon bonds for a purpose related to patient care.'' The commenter asked for consistent use of language as the Manual wording implies that interest expense for operating purposes, such as working capital, is also an allowable cost.

Response: The language in section 213(A) of the Manual is correct. Zero coupon bonds may be used to provide funds for either capital-related costs or operating costs, as long as the costs are for a purpose related to patient care. We have revised § 413.153(f)(1) to clarify that interest expense incurred to provide funds for ''patient care-related costs'' is an allowable expense.

Comment: One commenter suggested that in the final rule we reference a specific exception to our general policy on the liquidation of liabilities, established at section 2305 of the Provider Reimbursement Manual, since the actual payment of interest expense will not be made until the bonds mature.

Response: Section 2305 of the Manual requires that short-term liabilities be liquidated within 1 year of the end of the cost reporting period in which the liability is incurred, subject to certain specified exceptions. With zero coupon bonds, the interest accrues during the life of the bond but is not payable until maturity or redemption of the bond. Since there are no specified interest payments due during the life of the bond, the liability for payment does not occur until the bond matures or is redeemed. There is no short-term liability. We note, in section 2305, that it does not apply to zero coupon bonds until they mature or are redeemed.

Comment: One commenter objected to the language in § 413.153(f)(2), which specified that earned interest from zero coupon bonds must be offset against all allowable interest expense. The commenter's concern was that in the case of a bond defeasance (an advance refunding of debt) there are specific guidelines regarding the treatment of costs associated with advance refunding and with the allocation of investment income. These guidelines are laid out in the Provider Reimbursement Manual in sections 2806.G.1, 233, and 213. The commenter believed that the proposed regulations are in conflict with specific instructions for bond defeasance.

Response: The commenter is correct. In an advance refunding of debt (which includes bond defeasance), the investment income is offset against the interest expense of both the refunded debt and the refunding debt and is included in determining the gain or loss on the advanced refunding rather than included with other investment income and prorated under § 413.130(g)(2). We agree that some changes in the language of the regulations are needed to better reflect the treatment of investment income in an advance refunding. We have removed the reference to ''all'' in § 413.153(f)(2) and revised the section to indicate that if zero coupon bonds are purchased with the proceeds of an advance refunding, offset of the investment income is required under § 413.153(b)(2)(iii), but the investment income is not prorated under § 413.130(g)(2).

Comment: One commenter raised a question about the current applicability of the section of the memorandum dated December 22, 1989, that allowed a provider, under certain circumstances, to reopen or amend a cost report to specify the method to be used for reporting interest expense and income on zero coupon bonds issued before December 22, 1989.

Response: The memorandum dated December 22, 1989, provided that for interest from zero coupon bonds issued before December 22, 1989, that is reportable on a cost report that can be reopened on or after December 22, 1989, a provider could request amendment or reopening to specify the method of reporting the interest expense and income on the zero coupon bonds. The memorandum did not contain a time limitation on the requests. However, in order to effectuate an orderly implementation of these provisions, we are requiring providers to submit request for reopenings or amendments

within 60 days of publication of this final rule. Any request received after that date will be considered not timely filed and will not be honored.

V. Provision of the Final Regulations

This final rule adopts the provisions of the proposed rule as final, with the following minor revisions:

- In § 413.153(f)(1), we have changed the phrases ''capital-related cost'' to ''patient care-related cost'' and to ''provide funds'' rather than ''finance''.
- In § 413.153(f)(2), we deleted the word ''all'', rewrote part of the section for clarity, and added an appropriate cross-reference provision for handling zero coupon bonds purchased with the proceeds of an advance refunding of debt.

VI. Regulatory Impact

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5. U.S.C. 601 through 612) unless we certify that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider providers to be small entities.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside a metropolitan statistical area.

In the December 22, 1993 proposed rule, we concluded that the proposed rule changes would not have a significant economic impact on a substantial number of small entities, and would not have a significant impact on the operations of a substantial number of small rural hospitals. As discussed above, we received two letters of comments on the proposed rule, neither of which objected to our conclusion that these changes will not have a significant impact. This final rule adopts the provisions at the proposed rule with only minor technical changes. Therefore, we have determined, and certify, that this final rule will not have a significant economic impact on a substantial number of small entities. Also, this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we have not prepared a regulatory flexibility analysis or a rural hospital impact analysis.

In accordance with the provisions of Executive Order 12866, this final regulation was not reviewed by the Office of Management and Budget.

Under the provisions of Public Law 104–121, we have determined that this final rule is not a major rule.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the collection burden on the affected public, including automated collection techniques.

The overall recordkeeping and information collection burden associated with filing the provider cost report has been approved by OMB through August 31, 1996 under OMB No. 0938–0050.

In the December 13, 1993, proposed rule (58 FR 65150), we indicated that there would be no additional reporting burden on those providers who have zero coupon bonds and solicited comments. No comments were received.

Section 413.153 defines when interest expense is an allowable cost and how interest income is treated. The changes to this section represent a clarification of the current policy on interest expense and income as it applies to zero coupon bonds. It does not change the information collection and recordkeeping requirements. The information and recordkeeping required is that which is already required to file a cost report and approved by OMB as indicated above.

List of Subjects in 42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR chapter IV, part 413, is amended as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

A. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

Subpart G—Capital-Related Costs

B. Section 413.153 is amended by adding paragraphs (b)(4) and (f) to read as follows:

§ 413.153 Interest expense.

* * * * *

(b) *Definitions*—* * *

(4) *Zero coupon bonds.* Zero coupon bonds are issued by government agencies, corporations, and banks at a price substantially below the face value. The difference between the purchase price and the face value reflects the actual amount of interest and is neither a discount nor an adjustment to the interest rate as with other bonds. Interest is paid at maturity when the bond is redeemed at face value.

* * * * *

(f) *Zero coupon bonds*—(1) *Interest on bonds issued on or after August 15, 1996.* For zero coupon bonds issued on or after August 15, 1996, interest expense incurred to provide funds for patient care-related costs is an allowable expense, and interest income earned for investment purposes is an allowable offset, in the cost reporting period in which the interest accrues.

(2) *Interest income offset.* Interest income from zero coupon bonds must be offset against allowable interest expense as prescribed in paragraph (b)(2) of this section and in § 413.130(g)(2). If zero coupon bonds are purchased with the proceeds of an advanced refunding of debt, offset of the investment income is required under § 413.153(b)(2)(iii), but the investment income is not prorated under § 413.130(g)(2).

(3) *Use of effective interest method.* (i) Interest expense and interest income from zero coupon bonds that are reported as they accrue must be amortized using the effective interest method. This method recognizes the actual accrual of interest expense or income for each interest computation period (as specified by the bond instrument) throughout the life of the bond.

(ii) A constant effective yield rate is determined and applied to the book value (outstanding loan balance including prior accrued interest) of the bond at the beginning of each period to determine the total interest for the period.

(iii) If the interest computation period involves portions of more than one cost reporting period, the amount of interest for that computation period shall be apportioned to each cost reporting period.

(iv) An example of the computation of interest using the effective interest method follows:

Facts

Life of zero coupon bond: 15 years.

Value at maturity: $50,000.

Bondholder pays $6,996 for the bond.

Annual interest rate is 13.5506% compounded semi-annually.

From the table below, interest for the first year would be $980.11 ($474.00 plus $506.11).

Col 1 Six-month periods	Col 2 Book value beginning of period	Col. 3 Effective interest*	Col. 4 Book value end of period (columns 2 + 3)
1	$6,996.00	$474.00	$7,470.00
2	7,470.00	506.11	7,976.11
3	7,976.11	540.40	8,516.51
4	8,516.51	577.02	9,093.53
29	43,855.94	2,971.37	46,827.31
30	46,827.31	3,172.69	50,000.00

*Computed by multiplying the book value at the beginning of each period (Column 2) by 6.7753% (the annual interest rate of 13.5506% 2 = 6.7753%).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 23, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 96–17895 Filed 7–15–96; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

49 CFR Part 40

[OST Docket No. OST–96–1532]

RIN 2105–AC37

Amendments to Laboratory Certification Requirements

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: This final rule establishes provisions that would permit drug testing laboratories located outside the U.S. to participate in the Department's drug testing program. The Department of Transportation would take action permitting the laboratories to participate based on recommendations from the Department of Health and Human Services.

EFFECTIVE DATE: This rule is effective on July 16, 1996.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Room 10424, (202–366–9306); 400 7th Street, SW., Washington DC 20590; or Mary Bernstein, Director, Office of Drug Enforcement and Program Compliance, same street address, Room 10317, (202) 366–3784.

SUPPLEMENTARY INFORMATION: Recently, the Federal Highway Administration (FHWA) issued a final rule applying its drug and alcohol testing requirements to foreign-based drivers operating in the United States (60 FR 49322; September 22, 1995). Under the rule, Canadian and Mexican drivers who come into the United States will be subject to testing on the same basis as U.S. drivers, beginning July 1, 1996, for employees of larger carriers and a year later for employees of smaller carriers.

In any case, Canadian and Mexican employers who collect drug urine specimens under FHWA rules will be able to have the specimens tested in U.S. laboratories certified by the Department of Health and Human Services (DHHS), on the same basis as U.S. employers. In the interest of facilitating program implementation, the Department hopes that it will be possible for Mexican and Canadian laboratories to participate in the program as well. (If Canadian and Mexican laboratories are not authorized to participate in the program as provided in this rule, Canadian and Mexican employers must send specimens to DHHS-certified laboratories in the U.S. for testing.)

Canadian and Mexican laboratories may participate in the DOT-mandated testing program only if their participation is consistent with the Department's statutory authority. Strict safeguards for the accuracy and quality of laboratory tests are a key mandate of the Omnibus Transportation Employee Testing Act of 1991.

The motor carrier portion of the Act (49 U.S.C. 31306(b), which parallels the other modal sections of the Act), provides that, in carrying out the requirement to establish a motor carrier drug testing program , the Secretary ''shall'' develop requirements ''that shall''

(2) for laboratories and testing procedures for controlled substances, incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing—

(A) comprehensive standards for every aspect of laboratory controlled substances testing and laboratory procedures to be applied in carrying out this section, including standards requiring the use of the best available technology to ensure the complete reliability and accuracy of controlled substances tests and strict procedures governing the chain of custody of specimens collected for controlled substances testing; * * *

(C) appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform controlled substances testing in carrying out this section.

(3) require that a laboratory involved in testing under this section have the capability and facility, at the laboratory, of performing screening and confirmation tests; * * *

The language of these provisions is clearly mandatory, a point which the legislative history reinforces. Senate Report 102–54 (May 2, 1991), concerning S. 676, the bill that became the Act, notes, in response to concerns about testing accuracy and false positive tests, that ''By incorporating laboratory certification and testing procedures developed by HHS and DOT * * * the Committee has taken affirmative steps to ensure accuracy.'' (S. Rept. 102–54 at 7.) Later, in speaking of the laboratory and other safeguards in the bill, the report says that

These safeguards are critical to the success of any testing program. They are designed to ensure that * * * there is accountability and accuracy of testing. They provide what the Committee believes are the basic minimums * * * the Secretary is urged to carefully review the safeguards in any testing program to ensure they are adhered to in a vigorous manner. (*Id.* at 31)

More specifically on laboratory matters, the Committee said that

Incorporating the HHS guidelines relating to laboratory standards and procedures * * * as DOT has done in Part 40 * * * is an essential component of the procedural safeguards specified in this subsection.* * * Realizing that these guidelines may be subject to future modification, the Committee has acted to specify that the basic elements of certain provisions now in effect are mandated, including the need for comprehensive standards and procedures for all aspects of laboratory testing of drugs * * * [and] the establishment of standards and procedures