

GAO

**Fact Sheet for the Honorable
Charles E. Schumer, House of
Representatives**

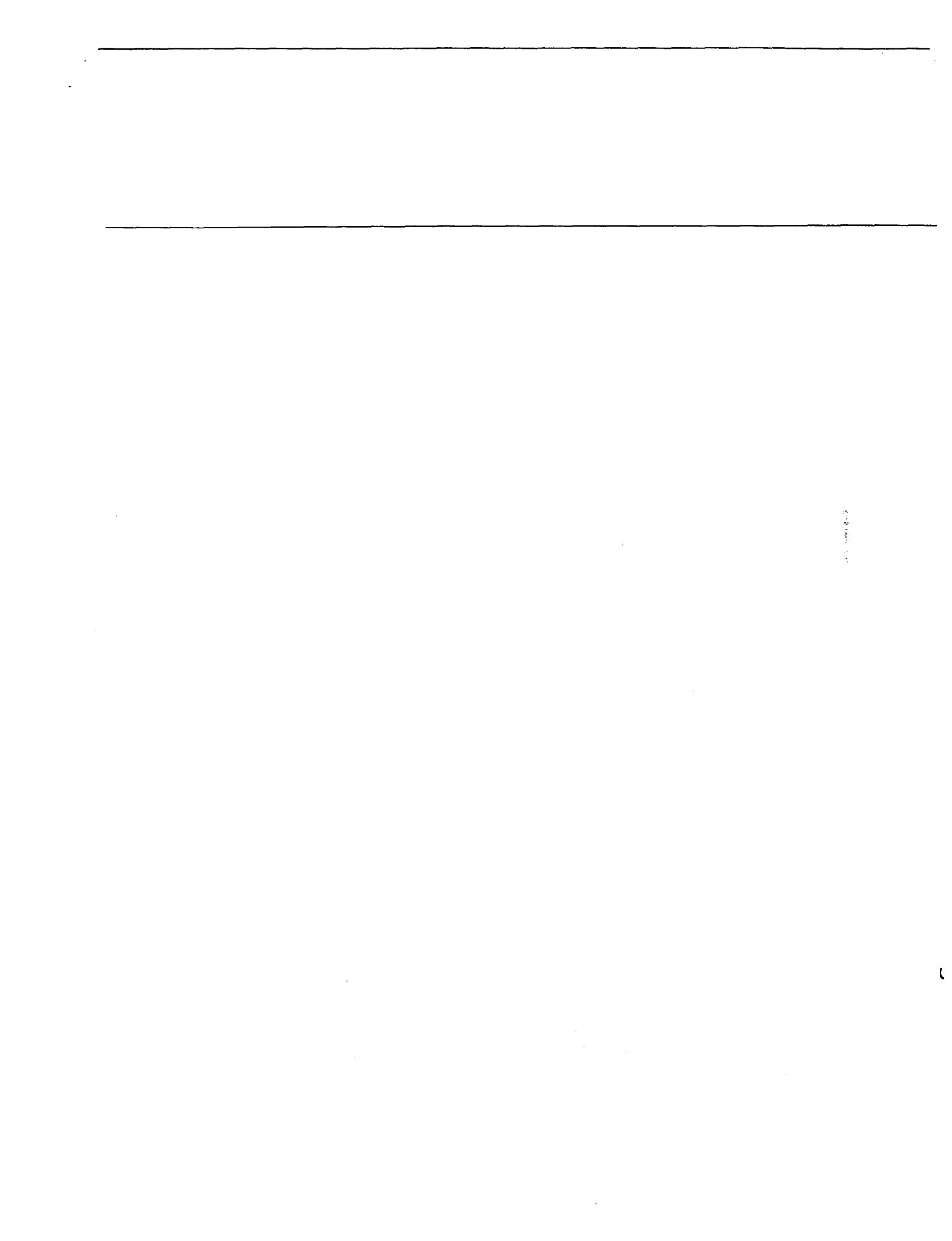
September 1988

**EMPLOYEE DRUG
TESTING**

**Regulation of Drug
Testing Laboratories**



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GAO

United States
General Accounting Office
Washington, D.C. 20548

General Government Division

B-223280

September 2, 1988

The Honorable Charles E. Schumer
House of Representatives

Dear Mr. Schumer:

In your December 7, 1987, letter, you noted that the dramatic increase in the use of employee and job applicant drug testing in the public and private sectors has raised concerns about the controls over testing procedures and whether sufficient care is taken to ensure that individuals are not harmed as a result of poor quality tests or inadequate policies and procedures. In that letter, you asked us to examine the status of controls over employee drug testing by determining (1) what federal and state laws and state licensing requirements regulate the operation of laboratories doing employee drug testing; (2) the extent to which professional associations or societies exercise guidance or standards over the quality and practices of drug testing laboratories; and (3) to the extent possible, how effectively drug testing is regulated in the United States and how regulation can be improved.

On August 16, 1988, we briefed your office on the status of our work, which is still continuing. At the meeting, your office asked us to provide in writing the information we have obtained so far on the extent and nature of state regulation over applicant/employee drug testing laboratories. This fact sheet responds to that request.

RESULTS IN BRIEF

We surveyed all 50 states on the nature of laws, regulations, and other legally enforceable provisions they have in effect to govern laboratories that do applicant and employee drug testing.¹ The survey results showed that there is no uniform nationwide

¹For reporting purposes, we include job applicant testing under the term "employee testing."

regulation of all laboratories that can do employee drug testing. Based on state survey responses about the extent to which they regulate employee drug testing laboratories, we found that laboratories doing employee drug testing are

- controlled in 11 states through statutes and regulations that are specific to employee drug testing,
- controlled in 15 states through general medical or clinical laboratory statutes and regulations that do not include specific drug testing requirements, and
- not controlled in 24 states.

The appendix provides a listing of states as well as a map categorizing the states by their regulation of employee drug testing laboratories.

The absence of statutes and regulations in the 24 states does not mean that all laboratories doing drug testing in those states are free from controls. As discussed on page 3, depending on the nature of their testing activities, laboratories in any state can (1) be covered by federal controls, (2) voluntarily adhere to standards prescribed by various professional associations, and (3) be indirectly affected by state labor laws.

In addition, eight states, including three that reported no state controls (California, Indiana, and Washington) and five that reported general medical laboratory controls (Florida, Illinois, Nevada, New Hampshire, and Pennsylvania) were considering specific employee drug testing proposals at the time of the survey. We do not have current information on the status of these proposals.

OBJECTIVE, SCOPE, AND METHODOLOGY

To gather information on the nature and extent of state controls, we sent a questionnaire to each state's public health director or another appropriate official. The questionnaire, first mailed in May 1988, concerned regulation of laboratories that analyze urine specimens for the detection of substance abuse drugs in employees. All states responded to the survey, and we contacted all states to verify selected information. We contacted federal officials at the Center for Disease Control, the National Institute on Drug Abuse, and the Health Care Financing Administration to learn what, if any, federal controls apply to laboratories doing employee drug testing. We also contacted the following professional organizations: the

American Association of Bioanalysts, the American Society of Internal Medicine, and the College of American Pathologists to determine their role in regulating laboratories doing employee drug testing.

STATUTES AND REGULATIONS VARY AMONG STATES WITH CONTROLS

The survey responses indicate that state controls governing drug testing laboratories vary among the 11 states that have specific employee drug testing laboratory statutes and regulations and among the 15 states that have statutes and regulations controlling general medical or clinical laboratories. Controls also vary between the two groups. For example, 10 of those 11 states with specific employee drug testing laboratory controls require that a confirmatory test be done on urine specimens that initially test positive. Seven of these states only permit the use of a gas chromatography/mass spectrometry (GC/MS) confirmatory test which is generally recognized to be more accurate than the initial screening test normally used to detect illegal drugs. The remaining three allow for other types of confirmatory tests as well as GC/MS. Also, 8 of the 11 states require that a chain of custody procedure be followed for each urine specimen from collection to final test to ensure the integrity of each specimen. None of the 15 states with general laboratory regulations have this chain of custody requirement to control specimens. Only one of the 15 states requires a confirmatory test, and it will accept various types of confirmatory tests including GC/MS.

DRUG TESTING LABORATORIES
MAY BE SUBJECT TO OTHER CONTROLS

Laboratories in the 24 states without employee drug testing laboratory controls, as well as laboratories in all other states, can be affected by federal statutes, regulations and guidelines, standards prescribed by professional associations, and state labor laws. Federal controls that can affect employee drug testing laboratories include the National Institute on Drug Abuse's (NIDA) Mandatory Guidelines for Federal Workplace Drug Testing Programs, the Clinical Laboratory Improvement Act of 1967 (CLIA), and Medicare regulations. The NIDA guidelines, however, apply only to laboratories doing drug testing of federal employees. CLIA applies to large scale laboratories that test specimens from other states (interstate commerce) for medical diagnostic and treatment purposes. Medicare regulations cover laboratories testing Medicare patients. Thus, even in states reporting to us that they had no applicable state statutes or regulations, laboratories that test federal employees or Medicare patients

or participate in interstate commerce would be governed by the relevant federal requirements.

We found that, despite differences, the NIDA, CLIA, Medicare, and individual state controls are generically similar in that they have laboratory standards on personnel, quality control, record keeping, and inspection. We did not assess the adequacy of these controls. We noted, however, that in its guidelines, NIDA said that neither the Medicare nor the CLIA provisions were sufficient to provide quality assurance for employee drug testing laboratories. The NIDA guidelines further state that, because of the need to ensure the protection of individual rights within the context of an employee drug testing program, NIDA developed separate laboratory standards to respond to the unique needs of employee drug testing. For example, NIDA's guidelines require that all positive results from an initial screening test for drugs be confirmed by GC/MS and that a chain of custody procedure from collection to final testing be followed for each specimen.

Further, it is possible that laboratories in all states, including the 24 without applicable statutes or regulations, can belong to professional associations such as the American Association of Bioanalysts, the American Society of Internal Medicine, and the College of American Pathologists. These organizations have standards or quality assurance programs that are generally applicable to any member medical or clinical laboratory whether it is or is not involved in employee drug testing. The College of American Pathologists is in the process of developing a program that specifically addresses employee drug testing.

In the instance of two states--Montana and Utah--that reported no statutes or regulations relating to laboratories doing employee drug testing for substance abuse, we noted that laboratories may be indirectly affected by state labor laws. Both states have statutory provisions that specify the conditions under which employers can do employee drug testing. These provisions include the need to (1) establish chain of custody procedures for employee specimens and (2) verify initial positive test results. These statutes apply to employers rather than to laboratories. We have not reviewed comparable statutes in the other states to determine the extent to which they might similarly affect employers or drug testing laboratories.

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As agreed with your office, we plan no further distribution of this fact sheet until 30 days from its date of issuance unless you publicly announce its contents earlier. After that time, we will make copies available to other interested parties upon request. If you or your staff have questions, please contact me on 275-8676 or Richard Caradine on 275-3532.

Sincerely yours,



L. Nye Stevens
Associate Director

STATE REGULATION OF EMPLOYEE DRUG TESTING LABORATORIES

Using the responses to a questionnaire sent to all 50 states, we divided the states into three groups based on their responses about the extent to which they regulate employee drug testing laboratories. The states that make up these groups are listed below and depicted in figure I.1.

STATES WITH SPECIFIC STATUTES AND REGULATIONS

The 11 states having specific statutes and regulations that govern laboratories doing employee drug testing are Connecticut, Iowa, Kansas, Maine, Maryland, Minnesota, Nebraska, New York, Oregon, Rhode Island, and Vermont.

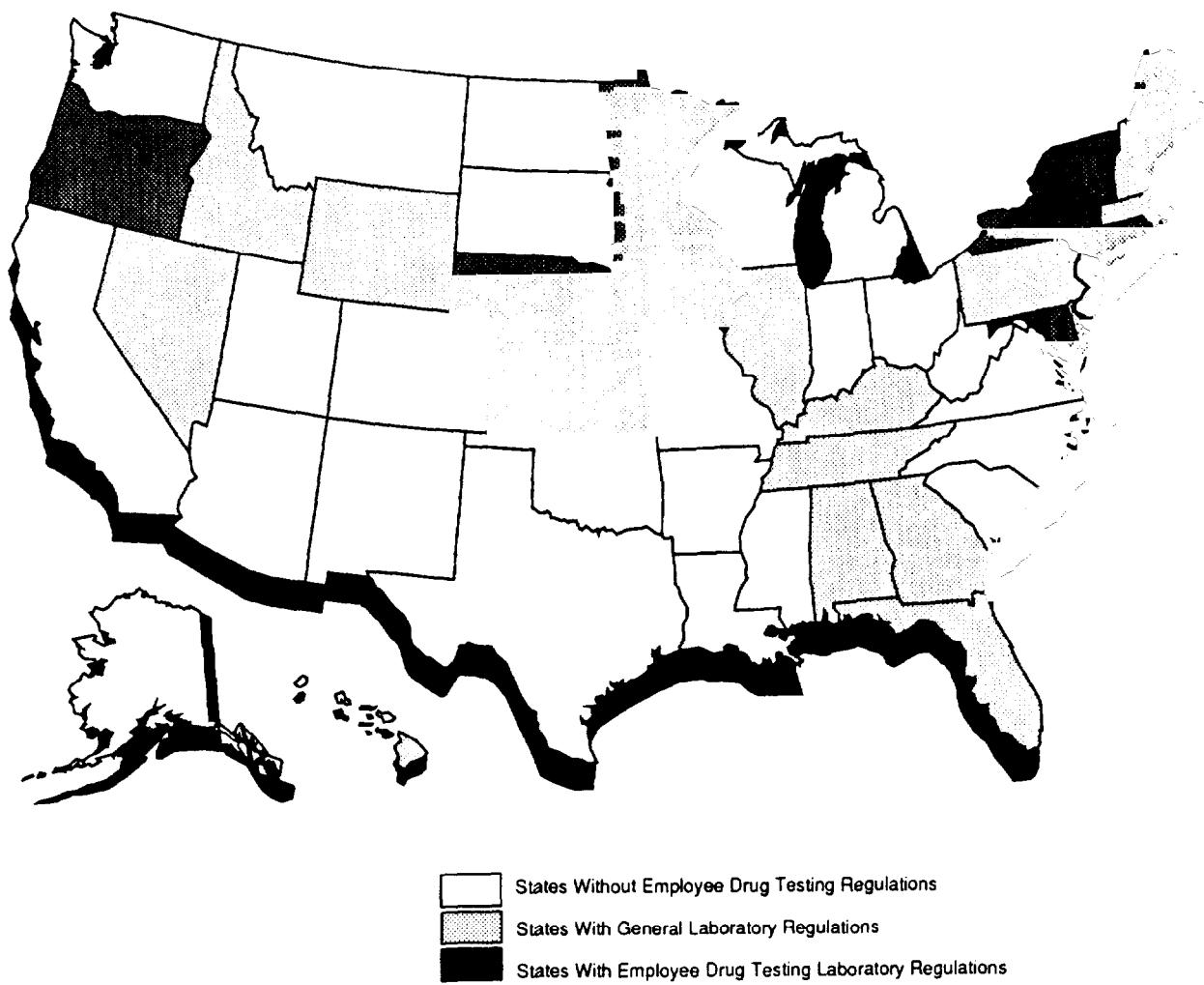
STATES WITH GENERAL STATUTES AND REGULATIONS

The 15 states that govern substance abuse urine testing through their general medical or clinical laboratory statutes and regulations, and which do not include specific requirements for employee drug testing are Alabama, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Kentucky, Massachusetts, New Hampshire, New Jersey, Nevada, Pennsylvania, Tennessee, and Wyoming.

STATES WITHOUT APPLICABLE STATUTES OR REGULATIONS

The 24 states that do not have statutes or regulations that govern laboratories doing employee drug testing are Alaska, Arizona, Arkansas, California, Colorado, Indiana, Louisiana, Michigan, Mississippi, Missouri, Montana, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

Figure I.1: State Regulation of Employee Drug Testing Laboratories



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