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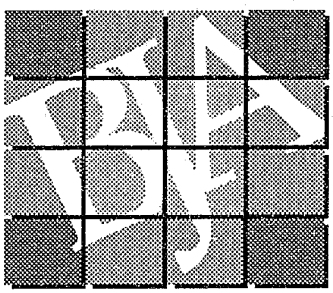
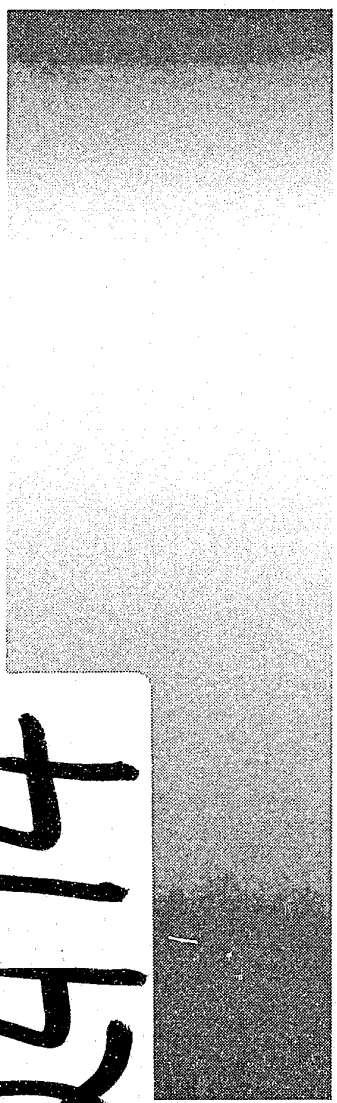


Bureau of Justice Assistance

Integrating Drug Testing Into a Pretrial Services System



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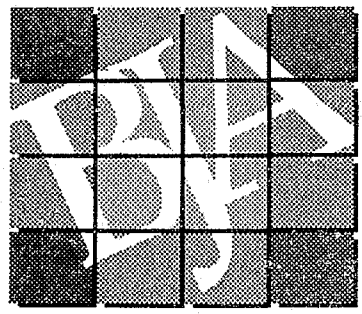

Bureau of Justice Assistance

Integrating Drug Testing Into a Pretrial Services System

MONOGRAPH

June 1993
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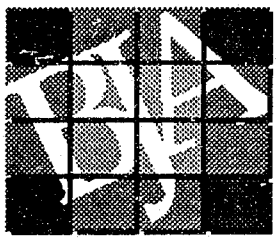

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EXECUTIVE SUMMARY

The information presented in this monograph is based on the experiences of the District of Columbia Pretrial Services Agency drug testing program, established in 1983 with a grant from the National Institute of Justice, as well as that of seven replication programs of the D.C. testing model, funded by the Bureau of Justice Assistance from 1987 to 1991.

The goal of pretrial drug testing, this monograph suggests, is to reduce the risks of failure to appear and of rearrest among drug-using pretrial defendants by identifying and monitoring drug use. The objectives of drug testing—the means of achieving this goal—are to maximize the number of identified drug users released to pretrial supervision by offering courts valid alternatives to detention or unsupervised release, reducing the level of drug use by monitored defendants, and separating defendants in need of drug treatment from those who can control drug use through monitoring alone.

Integrating Drug Testing Into the Court Process

Gaining support from criminal justice system representatives. Successful pretrial drug testing programs require the support of the major agencies in the local criminal justice system. These agencies must agree with the goals of the drug testing program and be in accord with their duties within the program's framework. To gain system support, program administrators must identify the important system representatives and their duties under pretrial drug testing, address these representatives' concerns, draft a Memorandum of Understanding outlining the duties of the system representatives, and maintain strong support for pretrial drug testing among these representatives.

Integrating drug testing into the risk assessment process. Pretrial programs must assess the risks posed by defendants who fail to appear in court or present a danger to the community if released. This assessment involves gathering information about each defendant and then extrapolating risk factors from that information.

Drug testing as a risk assessment tool has been applied in the pretrial drug testing demonstration programs at two different points, before the initial bond hearing and after the hearing. Specimens are collected from the defendant before the initial bond hearing in order to incorporate the test results into other information (such as criminal history, ties with the community, and other drug use information) in making a recommendation to the court. Specimens are collected after the initial bond hearing from defendants who have been ordered released and for whom no other indicator of drug use is present. The purpose is to determine whether testing or treatment should be a condition of release.

Together with other information about drug use obtained during the pretrial investigation, drug test results can be an effective tool in verifying a defendant's current level of drug use, as well as the risk of failure to appear, or of pretrial rearrest suggested by that level of drug use. Whatever risk assessment a pretrial program uses, to accurately determine a defendant's drug history, test results should be considered only in conjunction with other drug use information gathered before the trial.

Integrating drug testing into the supervised release process. A pretrial supervised release program involves the monitoring by program staff of defendants who have been released on their promises to abide by certain conditions. The conditions should be related to risks of failing to appear at scheduled court hearings and of presenting a danger to the community. The supervision of those conditions should be geared toward minimizing those risks. These same goals of minimizing identified risks should apply when integrating drug testing into a supervised release program.

Drug testing as part of a supervised release program is frequently referred to as pretrial drug monitoring and typically involves having defendants submit a urine specimen on a periodic basis. Program staff note the test results and whether defendants report as scheduled. Staff members counsel defendants who are testing positive or otherwise not complying and impose or recommend sanctions. Sanctions may include an increase in supervision levels, a referral to treatment, or notification to the court that the defendant has failed to comply with program requirements.

Drug testing appointments can be set on a regular schedule with defendants advised of the next appointment in advance, or on an irregular schedule with defendants receiving very short notice to report for testing. Guidelines must be established and consistently followed for responding to violations of the testing condition.

Operational Issues

Chain of custody. Chain of custody refers to procedures that govern the collection, handling, storage, testing, and disposal of a urine specimen to ensure a correct match to the person providing it; to safeguard against tampering or substitution of a specimen; and to document that these steps have been carried out.

To protect the chain of custody, facilities in which specimens are collected must meet privacy and security requirements. Chain of custody procedures should include detailed instructions on how to identify the person being tested, observe the voiding of the specimen, label the specimen, complete a collection witness log, transport the specimen to the testing facility, and test and dispose of the specimen.

Testing of urine specimens. Program administrators should have a basic knowledge of the technical aspects of testing urine specimens for drugs of abuse. The most important factor to consider when selecting a testing technology or instrument is whether it has gained general acceptance in the scientific community. Testing can be conducted in-house or by contract with an outside laboratory. An in-house facility offers the advantage of speedier processing and simplified chain of custody procedures. Outside laboratories offer the advantage of trained, experienced technicians and a staff toxicologist as supervisor. The advantages and disadvantages to each approach should be weighed in light of a pretrial program's resources and needs.

Confidentiality. Maintaining confidentiality means limiting access to test results and other program information on the defendant. Confidentiality further means limiting the use of such information to agencies and persons with accepted access and for accepted purposes.

Under limited circumstances, programs can release information to other parties, but only as needed to carry out a specific duty involving the defendant. Release of information to anyone other than parties to the Memorandum of Understanding requires the defendant's written consent and a legitimate reason for requesting the information. Programs should have written procedures for releasing information.

Drug testing programs that receive Federal assistance, such as Federal funding or exemptions from Federal taxes, must conform to confidentiality guidelines outlined in Federal rule 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule. All drug testing programs must conform to applicable State and local guidelines, which can be more restrictive than the Federal rule.

Management Issues

Staffing. A drug testing program requires an adequately sized and trained staff to perform its functions. There should be enough staff to observe chain of custody requirements during collection and transport of urine specimens to the laboratory. The staff should be able to test specimens, process program information, and supervise defendants ordered into pretrial drug monitoring.

The jobs common to a pretrial drug testing program are a program supervisor, specimen collectors, drug testing technicians, supervision officers, and data entry staff. Programs with automated information systems may wish to hire a system administrator to maintain the information system. The existing staff should be part of and approve any decision to add new duties to their existing jobs.

Training of staff is important and can take several forms and proceed at several levels. Program administrators should set up a training program to acquaint

supervisors with program policies and procedures. Supervisors in turn should train collectors and data entry staff. Testing technicians should be trained and certified by the testing equipment manufacturer.

Information system. Drug testing requires an information system for recording program information, reporting information to other parties, monitoring defendants in drug testing, and protecting the confidentiality of test results. This information system should provide program administrators with the means to organize, research, and control the operations of the drug testing program.

An information system can be manual, automated, or a combination of both. Whether a program uses a manual or an automated information system depends on the anticipated volume of testing, the type and capacity of its current system, and its anticipated use of the information system.

Procedures manual. A procedures manual describes all the pretrial drug testing program's policies and procedures. It is a training guide for new employees and a reference for current employees and persons outside the program. The manual should note which person or unit is responsible for carrying out each function. It should be written to be easily understood by persons unfamiliar with the program. Sections should be brief, with technical terms explained, and should follow a defendant's progress through the program.

Sections of the manual should include the dates the procedures went into effect. The manual should accommodate changes in program procedures and should be updated whenever procedures change. Updates should note the staff affected by the change and any new forms or computer entries required.

Legal Issues

Legal considerations in pretrial testing. Program administrators planning to integrate drug testing into their pretrial systems should note that pretrial drug testing is not a settled area of the law and that every facet of drug testing is open to legal review. Drug testing has been found to constitute a search under the fourth amendment, and lower courts have ruled that drug testing complies with substantive due process when collection and testing procedures are reasonable.

No court has yet determined that pretrial drug testing affects the right to equal protection of the law. In future, however, pretrial drug testing programs may have to show that defendants recommended for pretrial drug monitoring would otherwise be likely to continue using drugs. Drug testing programs should provide a verbal and written explanation of the drug test before requesting the arrestee's consent.

Before undertaking drug testing, program administrators are advised to consult their jurisdiction's attorney for an opinion.

INTRODUCTION

Interest in drug testing[1] has expanded in the pretrial services field for several reasons. First, current drug use is a reliable predictor of pretrial misconduct by drug-using arrestees. Second, drug testing before the initial bond hearing can help identify a drug user's potential risk to the community.[2] And third, drug testing as a condition of pretrial release can help reduce pretrial misconduct.[3]

The information presented in this monograph is based on the experiences of the District of Columbia Pretrial Services Agency drug testing program, established in 1984 with a grant from the National Institute of Justice (NIJ),[4] as well as that of seven replication programs of the D.C. testing model, funded by the Bureau of Justice Assistance (BJA) from 1987 to 1991.[5] These programs were introduced in:

- Pima County, Arizona.
- Multnomah County, Oregon.
- New Castle County, Delaware.
- Prince George's County, Maryland.
- Maricopa County, Arizona.
- Milwaukee County, Wisconsin.
- Los Angeles County, California.

This monograph henceforth refers to these and the D.C. program collectively as the demonstration programs.[6]

The D.C. program defined pretrial drug testing as a combination of pre-initial-appearance screening and pretrial drug monitoring. Pre-initial-appearance testing occurs before the initial bond hearing; the test results help the pretrial program formulate a recommendation for pretrial release or detention. Pretrial drug monitoring is drug testing ordered as a condition of pretrial release. The experiences of the replication programs show that pre-initial-appearance testing and pretrial drug monitoring are distinct and independent components, each tied to a basic role of a pretrial program: identifying potential risks of pretrial failure (pre-initial-appearance testing) and controlling risk through conditional release (pretrial drug monitoring).

The most critical element of pretrial drug testing is a pretrial services program (or comparable agency or agencies that provide such services). The pretrial services program provides to the court, before the initial bond hearing, verified community ties and criminal history information on defendants; the program also supervises pretrial defendants. This agency should be responsible for identifying drug-using defendants before the initial bond hearing, integrating drug testing into the current supervised pretrial release scheme, and overseeing the drug testing and supervision functions.[7]

BJA has highlighted the importance of pretrial programs for effective pretrial drug monitoring:

> Formal pretrial services agencies provide an extremely valuable service to prosecutors and the courts by conducting a thorough risk assessment, recommending pretrial disposition, and performing intensive monitoring of the arrestee. Such agencies are critical in effectively administering pretrial drug testing, meeting special needs of the criminal justice system in response to drug abusing offenders[,] . . . and serving as coordinator between the system and various programs that fall in the category of intermediate sanctions.[8]

Program Goals and Objectives

The goals of a pretrial drug testing program should be grounded in the goals or mission statement of the pretrial services program and should augment the services that the program furnishes to its criminal justice system, such as gathering information on the defendant, preparing a report assessing the

likelihood of rearrest or failure to appear, recommending appropriate options for conditional release, and supervising conditions of pretrial release and reporting violations to the court.[9]

A pretrial drug testing program's objectives—the means of obtaining the goal—should be specific, measurable, and consistent with the following pretrial program objectives: developing options that permit judicial officers to maximize the rate of nonfinancial release, minimizing failures to appear in court, and reducing inequities in the pretrial services system.

The goal of pretrial drug testing, this monograph suggests, is to reduce the risks of failure to appear and of rearrest among drug-using pretrial defendants by identifying and monitoring drug use.

The objectives of pretrial drug testing—the means of achieving this goal—are to maximize the number of identified drug users released to pretrial supervision by offering courts valid alternatives to detention or unsupervised release, reducing the level of drug use by monitored defendants, and separating defendants in need of drug treatment from those who can control drug use through monitoring alone.

The purpose of this monograph is to provide criminal justice professionals—specifically pretrial services program administrators—with a reference document that will help them implement pretrial drug testing programs in their jurisdictions. The monograph discusses the elements needed for integrating drug testing into a pretrial services system.

How This Monograph Is Organized

The experiences of the jurisdictions integrating drug testing into their pretrial services systems show that certain elements are critical for success. These elements fall under four general categories: integrating drug testing into the court process, operational issues, management issues, and legal issues. Chapters in the monograph are grouped under these categories and describe how pretrial agencies incorporating drug testing into their programs can deal with the issues. Each chapter ends with a summary of the key points covered.

Notes

1. Drug testing here refers to testing urine for signs of specific drugs using either immunoassay or chromatography technologies.

2. Eric Wish, "Drug Use Forecasting: New York, 1984 to 1986," Washington, D.C.: U.S. Department of Justice, National Institute of Justice, February 1987; A. Yezer, R.P. Trost, and M. Toborg, *The Efficiency of Urine Test Results in Risk Classifications of Arrestees, Monograph 6: Assessment of Pretrial Urine Testing in the District of Columbia*, Washington, D.C.

3. John A. Carver, "Drugs and Crime: Controlling Use and Reducing Risk Through Testing," *NIJ Reports*, September/October 1986.

4. The D.C. pretrial drug testing program was the first to test arrestees before the initial bond hearing and provide weekly in-house drug testing as a condition of pretrial release.

5. The sites chosen in 1987 under the Detection and Monitoring of Drug-Abusing Arrestees (DMDA) grant (#86–SD–CX–K044) were Pima County, Arizona; Multnomah County, Oregon; and New Castle County, Delaware. In 1988, BJA selected three additional pretrial programs under the Drug Testing Technology and Transfer (DTTT) program (grant #87–DD–CX–K062): Prince George's County, Maryland; Maricopa County, Arizona; and Milwaukee County, Wisconsin. In 1988, BJA selected Los Angeles County to join the existing programs in Pima County, Multnomah County, Milwaukee County, Maricopa County, and Prince George's County under the Drug Testing and Intensive Supervision (DTIS) grant (#88–MU–CX–0002).

Only the D.C., Prince George's County, and Los Angeles County programs received local funding to continue pretrial drug testing at the end of the Federal grants. Multnomah County continued pretrial drug monitoring under the BJA-funded Comprehensive Drug Testing Project (grant #90–DD–CX–0029).

6. Under the Anti-Drug Abuse Act of 1988 (PL 100–690), the U.S. Congress also mandated pretrial drug testing in eight selected Federal court districts (Texas Western, Florida Middle, Michigan Eastern, Nevada, New York Southern, Arkansas Eastern, North Dakota, and Minnesota) as a 2-year demonstration project. In a subsequent report, the Administrative Office of the United States Courts advocated expanding pretrial drug testing to all Federal court districts. (*Final Report of the Director of the Administrative Office of the United States Courts on the Demonstration Program of Mandatory Drug Testing of Criminal Defendants*, Administrative Office of the United States Courts, March 29, 1991.)

7. Several agencies can perform different functions related to pretrial drug testing. For example, a TASC program can collect and test urine specimens as well as offer various treatment options. This was the approach used by the Maricopa County and Multnomah County replication programs. While different agencies can have a hand in the program, the pretrial services agency should have administrative oversight. Owing to its oversight responsibility, a pretrial agency should ensure that a contracted laboratory complies with specific procedures for collecting and testing specimens and reporting drug test information. (For more information on TASC programs, consult the BJA publication, *Treatment Alternatives to Street Crime, TASC Programs: Program Brief.)*

8. Bureau of Justice Assistance, *Edward Byrne Memorial State and Local Law Enforcement Assistance Program: Fiscal Year 1991 Discretionary Program Application Kit,* Washington, D.C.: U.S. Department of Justice, February 1991, p. 233.

9. National Association of Pretrial Services Agencies, *Performance Standards and Goals for Pretrial Release and Diversion, Standard X,* Washington, D.C.: National Association of Pretrial Services Agencies, 1978.

PART ONE:
INTEGRATING DRUG TESTING INTO THE COURT PROCESS

CHAPTER I.
GAINING SUPPORT FROM CRIMINAL JUSTICE SYSTEM REPRESENTATIVES

Successful pretrial drug testing programs require the support of the major agencies in the local criminal justice system. These agencies must agree with the goals of the drug testing program and be in accord with their duties within the program's framework. Support must come both from outside criminal justice agencies and from existing pretrial services staff. To gain system support, program administrators must:

- Identify the important system representatives and their duties under pretrial drug testing.
- Identify and address these representatives' concerns.
- Draft a Memorandum of Understanding outlining the duties of the system representatives.
- Maintain strong support for pretrial drug testing among these representatives.

Identifying System Representatives

Major system representatives are the heads of criminal justice agencies that perform a function under drug testing or whose support is crucial to the drug testing program's success. They usually come from several agencies, and each plays a particular role and should agree to the limits of that role.

The *local court* will order defendants into the drug testing program. Judges should agree to follow program guidelines when ordering defendants into drug testing and to use program information only to set conditions of pretrial release and sanctions for violating pretrial release conditions.

The *local prosecutor* should agree not to use program information to determine guilt in a pending case or to file new charges. Prosecutors in some jurisdictions may also perform other program-related functions. For example, in Maricopa County, the prosecutor brings requests for revocation of pretrial release.

The *local public defender or defense bar* may enter early agreements with the pretrial drug testing program to help preclude future challenges to the program.

The *sheriff* or *jail administrator* must give specimen collectors access to arrestees. Program administrators should note which agency really has custody over arrestees. For example, in Milwaukee County the police have jurisdiction over defendants until the initial court appearance.

Existing pretrial program staff must be kept informed by program administrators and, where appropriate, should be involved in planning the new drug testing program. Administrators may assume staff share the goals of drug testing or will accept new responsibilities as part of their jobs. However, staff persons made to perform drug testing functions may do these jobs poorly or not at all. Administrators should seek staff support for drug testing as vigorously as they do external support.

There are other major representatives as well, including contracted laboratories, treatment facilities, funding sources and funding approval agencies, and other drug testing programs.

For instance, *contracted laboratories*, if used, must agree to follow proper chain of custody procedures when collecting and testing specimens. They must agree to test specimens using scientifically approved technology, deliver test results to the pretrial program promptly, and release test information only to the pretrial program.

Programs may also want *treatment facilities* to reserve beds for defendants requesting or ordered into drug treatment. Treatment facilities must agree to release defendant compliance information to the pretrial program.

Programs may be dependent on *funding sources and funding approval agencies*. They must identify the agencies that are funding pretrial drug testing and

their attitudes about pretrial drug testing. Specifically, what does the funding agent hope to gain from drug testing? For instance, does the agent want to determine the existence of a drug abuse problem in the arrest population, or to allocate available treatment resources more efficiently? Programs must also gauge the opinion of agencies that approve contracts with laboratories or Federal funding sources. For instance, in Multnomah County, the county counsel must approve all county agency contracts. In this case, the counselor gave the pretrial program a detailed list of concerns about a pretrial drug testing program and asked program officials to respond.

Finally, *other programs with drug testing grants* affecting defendants (such as a probation department) may feel encroached upon by a pretrial drug testing program. Program administrators should find out if other agencies are involved with similar grants and explain the pretrial drug testing program to them.

Identifying and Addressing Representatives' Concerns

At the outset, program administrators should notify system representatives of the pretrial program's intent to explore the feasibility of pretrial drug testing. The notice should state generally why the program is considering drug testing (for instance, because it was ordered by the chief judge or local executive or is part of a State drug control strategy), how the program will be structured, and what duties system representatives may be asked to perform. The notice should also solicit general opinions on pretrial drug testing.

After receiving opinions from system representatives, program administrators should respond to concerns that arise. This may involve drafting policies to address specific concerns. For example, the Prince George's County program developed separate sanctions policies for defendants charged with violent offenses. They did this because the local prosecutor feared the program would supervise possibly dangerous felons. The Multnomah County program's policy included several sanctions short of a request for revocation of release; this helped allay the local sheriff's concern that all defendants violating the drug condition would have their bonds revoked, thus adding to jail crowding.

Programs may also find it expedient to form advisory boards to discuss program procedures and implementation problems.

Responding to the media. Program administrators should be prepared to respond to media inquiries about the pretrial drug testing program and to decide what form these responses should take. During the planning stage, several demonstration programs either informed the media of the drug testing program or received media inquiries. Program administrators, along with the court, decided during the planning phase what was appropriate to say. This same caution is suggested for administrators of future drug testing programs. Negative coverage may result if the program administrator or other designated media contact person appears reluctant to discuss pretrial drug testing or is secretive about the proposed drug testing program. However, program administrators should not overstate what will happen before all the system representatives have come to agreement about the program's operations. During the planning stage, one option might be to defer all media inquiries about the pretrial drug testing program to a spokesperson for the funding agency.

One example of positive media coverage was an open house given by the D.C. pretrial program. Program administrators made the in-house testing laboratory available for one afternoon to the media, judges, and attorneys. Members of the media were walked through the various stages of the program, from identifying defendants reporting for testing to running tests on laboratory machinery. The program supervisor explained the goals of the drug testing program and answered the questions posed.

Responding to public defender concerns. Certain agencies may be cautious of supporting drug testing if the local public defender opposes it or threatens legal action. Program administrators should be prepared to respond quickly to a public defender's questions about pretrial drug testing. Specifically, they should be prepared to tell how the drug testing program will respect defendants' privacy and due process rights and restrict the use of program information.

Once this groundwork of support has been laid, it is time to document the agreements reached, through the Memorandum of Understanding.

The Memorandum of Understanding: Purpose and Parties

The Memorandum of Understanding is a formal agreement that defines the duties of each party involved in a drug testing program. Parties enter into the Memorandum before the drug testing program begins. Besides the pretrial program, these parties include the local judiciary, the prosecutor and public defender, the contracted laboratory, the sheriff or jail administrator, and local law enforcement officials. Other departments, such as probation, should be considered for involvement if they perform a duty under drug testing or receive drug test information.

The Memorandum includes only the general duties of each party and not specific procedures that might change frequently (for instance, the pretrial program agrees to collect specimens from arrestees, report test result information to the court and other parties, and monitor defendants placed into drug testing).

The Memorandum should also describe the pretrial program's policy for general release of information and the limits on the parties' use of program information. Usually, the local court agrees to use drug testing information only to set bond or in condition violation hearings, and the local prosecutor agrees not to consider test information on the question of guilt. The Memorandums for the demonstration programs also had brief forewords stating the goals of the drug testing programs. If a program is of a limited duration, the foreword should include the time it is in effect.

All parties, except the public defender, must sign the Memorandum to demonstrate their agreement to the duties assigned to them and to the pretrial drug testing program's general operations.

Memorandum Agreements on Duties of the Parties

The following are examples of provisions in the demonstration programs' Memorandums concerning duties of the parties.

The pretrial drug testing program agrees to:

- *Target defendants for pre-initial-appearance testing and recommend defendants for pretrial drug monitoring.* If the pretrial program does pre-initial-appearance testing, it decides which defendants are asked to give a specimen. If the program does not perform pre-initial-appearance testing, it describes the method used to recommend testing as a release condition. The Pima County and Maricopa County programs recommended defendants for supervised testing using a profile of drug-using defendants most likely to have used drugs prior to arrest. The Multnomah County program recommended supervised testing for defendants if there was a current indicator of drug use (such as self-admission), prior history of drug use, or a present drug charge. Each program developed these methods based on research done when the program conducted pre-initial-appearance testing.
- *Monitor defendants the court orders into pretrial drug monitoring and notify the court of test results.* The Memorandum should give a general description of the frequency of testing and should identify sanctions available for violations of the testing condition. The sanction levels should start with internal sanctions (within the program) for initial violations and increase to formal sanctions for repeated or serious violations. The final sanction should be a request for bond revocation (see Chapter III, Integrating Drug Testing Into the Supervised Release Process).
- *Refer defendants to treatment programs.* Programs assess the treatment needs of defendants placed in pretrial drug monitoring and offer treatment as an option for supervised defendants.

The pretrial program, or the outside laboratory it uses for urine testing, agrees to:

- *Follow proper chain of custody requirements when collecting and testing specimens.* The program or laboratory should follow approved guidelines for collecting, transporting, and testing specimens (see Chapter IV, Chain of Custody).

- *Follow proper protocol when operating testing instruments, including using uniform cutoff levels.* The program or laboratory should also follow the testing instrument manufacturer's protocol for calibrating, operating, and maintaining the testing instrument.
- *Provide test results to the pretrial program in a timely manner and release test information only to the pretrial program.* Contracted laboratories should deliver pre-initial-appearance test results to the pretrial program in time for initial appearance in court, and supervised testing results should be delivered within 24 hours. With the exception of research studies, contracted laboratories should never release test information to parties other than the pretrial program.[1]
- *Retest or confirm initial positive results before reporting them, and confirm disputed specimens.* The pretrial program or laboratory should, at the least, retest initial positive specimens using the same technology. The program or laboratory should also confirm, using an alternate technology, any specimens disputed by a defendant or to be used in a condition violation hearing.

The prosecutor agrees not to use test results to determine guilt in the pending case or to file new charges. This conforms to State bail statutes prohibiting the use of pretrial program information on the question of guilt (such as the bail statute for Washington, D.C.) and to Federal rules on the confidentiality of drug test information forbidding agencies from using such information to prosecute defendants in drug programs (see Chapter VI, Confidentiality.)[2]

The court agrees to use test results to determine pretrial release, to decide sanctions for violation of pretrial release, and to modify bond. Courts should also consider a defendant's compliance with the drug testing condition at sentencing.

The sheriff or head of the local jail agrees to give urine collectors access to incarcerated defendants.

The public defender (or local defense bar), if included in the Memorandum, agrees to the general goals of the drug testing program and the stipulations for access to program information. The public defender (or local defense bar) usually plays no role in pretrial drug testing, but a program may want to include this system representative in the Memorandum.[3]

Probation departments agree to use drug test information for presentence investigations and to fashion appropriate drug monitoring or treatment supervision.[4]

Treatment facilities agree to inform the pretrial program of the defendant's compliance and to give the program access to the defendant's treatment records for the pending case. Treatment facilities that perform drug testing might also agree to test defendants regularly and submit the results to the pretrial program.

Memorandum Agreements on Release of Information

The Memorandum of Understanding should include a general outline of the pretrial drug testing program's policy on release of information, which should describe when and to whom the program will release information without a consent form signed by the defendant. Generally, programs should:

- *Give test results to the court, prosecutor, and defense attorney at initial appearance and when asking for bond modification.* Programs may also give results to these parties at each scheduled court appearance.
- *Give a defendant's attorney open access to test information, with the understanding that the attorney uses it only in the pending case.* Programs should also send defense attorneys copies of violation requests and dates for violation hearings whenever programs send copies to the court and prosecutor.
- *Give test information—such as dates of positive tests—to prosecutors after each positive test, provided the prosecutor agrees to use the information only to request changes in bond.*
- *Give information to probation departments only for presentence investigations.*
- *Release information to other agencies or in other circumstances only when a consent form has been signed by the defendant.*

Updating the Memorandum of Understanding and Maintaining Support

A program should update its Memorandum whenever the duties of a party change or when another party is added. For minor revisions (changing or adding to the duties of one party, for example), programs can draft an addendum to all parties explaining the change or addition. When a party is added to the Memorandum, the addendum should include the duties of the party, an indication of when the new party will receive test information, and a space for the party's signature. An enclosed letter could explain the change or addition and the reasons for it and advise parties to contact the pretrial program if they do not approve of the change. Programs making major changes to the Memorandum (such as changing basic policies or the duties of more than one party) should rewrite the document and circulate it for signatures.

In addition to keeping the Memorandum up to date, programs should take steps to maintain the level of support given before pretrial drug testing is integrated. Due to the pace of the court or the importance of other functions, system representatives may not perform drug testing duties quickly or at all. Program administrators should maintain contact with the heads of major agencies to correct these problems as they occur.

The importance of maintaining strong contacts with system representatives was highlighted in Multnomah County. While the local court initially endorsed pretrial drug testing, the condition was not used often.[5] However, program administrators maintained regular contact with the court's chief judge. Because he supported the drug testing program, the chief judge signed an order making drug testing an automatic release condition for all eligible defendants. With this order in effect, judges ordered close to 40 percent of eligible defendants into the program in the months that followed.

Summary of Major Points

- Successful pretrial drug testing programs must have the support of the major agencies in the local criminal justice system, including local court representatives, the local prosecutor, the public defender or local defense bar, and the sheriff or jail administrator. Other important representatives include the laboratory used to test urine specimens, local treatment facilities, funding sources, and programs with similar testing grants.
- Program administrators should notify system representatives of the pretrial program's intent to explore pretrial drug testing. The notice should generally state why the program is considering drug testing, how testing will be structured, and what duties system representatives may be asked to perform. The notice should also solicit general opinions on pretrial drug testing.
- Program administrators should address concerns that arise and consider drafting policies on these specific concerns or forming advisory boards to discuss program procedures and any implementation problems.
- The Memorandum of Understanding is a formal agreement among the parties involved in pretrial drug testing. It outlines the duties of each party and describes the pretrial drug testing program's general policy on the release of information, including the boundaries for each party's use of test information.
- Parties to the Memorandum are the pretrial program, the contracted laboratory (if used), the local judiciary, the prosecutor, the public defender, and the sheriff or jail administrator. Probation and other departments are parties to the Memorandum if they perform a drug testing function or receive program information.
- Under the Memorandum, the pretrial program agrees to target defendants for testing and to submit results to court for bond hearings or bond review hearings. The program or its contracted laboratory agrees to perform urine collection and testing under acceptable protocol. The court and prosecutor agree not to use test results on the question of guilt or to file new charges. The sheriff or jail administrator agrees to allow the pretrial program or laboratory access to defendants for testing.
- Generally, a program gives test results to the court, prosecutor, and defense attorney at initial appearance and when asking for bond

modification. A program may inform the prosecutor that a defendant tested positive on certain dates, provided the prosecutor agrees to use the information only to move for bond modification.

- Release of information not described in the Memorandum or to parties not mentioned in the Memorandum requires a consent form signed by the defendant.

Notes

1. Since pretrial programs are responsible for releasing pretrial supervision information, they are the ones to respond to subpoenas for drug test information.

2. 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule, *Federal Register*, vol. 52, no. 110, June 1987.

3. In only one demonstration program jurisdiction did the public defender sign the Memorandum. Others usually did not want to agree to a program whose legality they might later challenge in court.

4. The D.C. program also gives probation officers test results before the initial bond hearing. This allows the officers to update their supervision records. The program has an agreement with the probation department that test results will not be used in probation revocation matters. The Los Angeles County program allows the jurisdiction's probation department to use pretrial drug test results in probation revocation hearings for defendants already on probation and convicted in the pending case. However, because test results released in these ways could still be used for revocation purposes, probation departments should have access to drug tests only for presentence investigations and development of appropriate supervision plans.

5. From January to June 1988, judges referred 269 of 1,990 (14 percent) defendants eligible for pretrial drug monitoring to the drug testing program.

CHAPTER II.
INTEGRATING DRUG TESTING INTO THE RISK ASSESSMENT PROCESS

Pretrial programs must assess the risks posed by defendants who fail to appear in court or present a danger to the community if released. This assessment involves gathering information about each defendant and then extrapolating risk factors from that information. Information is typically gathered by interviewing the defendant, interviewing reference persons to verify the information provided by the defendant, and checking various criminal justice information systems to establish criminal history. Drug use information, which is one factor often examined in the risk assessment process, is traditionally obtained through interviews with the defendant and reference persons, through discussions with probation or parole officers, and through the criminal history check.

While useful in identifying drug use, these traditional means of information gathering have limitations. The interview with the defendant may reveal a detailed history of drug use, but the defendant may not be candid about current and prior use. An examination of the complete criminal record may reflect a lengthy list of drug offenses, but it is possible that many drug-using arrestees will not have such records. A discussion with the defendant's references or probation or parole officers may provide insight into the defendant's drug use. However, sometimes even these persons may be unaware of the extent of the defendant's drug problem.

Drug testing constitutes another means of obtaining drug use information. Testing provides an objective, scientific measurement of a defendant's recent use of drugs. Testing compensates for many of the limitations of the traditional means of gathering drug use information; it does not depend on the defendant's truthfulness about drug use, the criminal record's reflection of use, or the knowledgeability of references or probation and parole officers regarding use.

However, a drug test is not an absolute means of measuring drug use and is subject to its own limitations. As discussed fully in Chapter V, Testing of Urine Specimens, a drug test result tells only whether a detectable level of a drug for which a test was run was found in the specimen provided. Because of the individual limitations of all these means of gathering information, the best course is to use a combination of all of them.

Drug testing as a risk assessment tool has been applied in the pretrial drug testing demonstration programs at two different points, before the initial board hearing and after the hearing. At each point, information is provided to a judicial officer who is considering or reconsidering release conditions. The only distinction lies in when the testing takes place, for in both cases, drug testing is used to assess risk. This form of testing should not be confused with pretrial drug monitoring, discussed in Chapter III, Integrating Drug Testing Into the Supervised Release Process, in which defendants are monitored to ensure they remain drug-free while on release awaiting trial.

Specimens are collected from the defendant *before the initial bond hearing* in order to incorporate the test results into other information (such as criminal history, ties with the community, and other drug use information) in making a recommendation to the court.

Specimens are collected *after the initial bond hearing* from defendants who have been ordered released and for whom no other indicator of drug use is present. The purpose is to determine whether testing or treatment should be a condition of release.

Pre-Initial-Appearance Testing

Two issues must be addressed when testing is done before the initial appearance. The first involves the population to be targeted for testing, and the second involves the integration of test results into the recommendation scheme.

Several possibilities are available when selecting the population to be targeted for testing. Program administrators can decide to target all those for whom a risk assessment is being conducted. If the program currently interviews, investigates, and provides a risk assessment on all new arrestees—misdemeanor and felony alike—a decision can be reached to add testing to that information-gathering process. Another option is to target a subset of the entire population. For example, perhaps only defendants charged with felonies would be targeted for testing. Of the six demonstration programs that have conducted pre-initial-appearance testing, four (Washington, D.C., Prince George's County, Multnomah County, and Milwaukee County) included felony and misdemeanor arrestees in their target populations, and two (Pima County and Maricopa County) included felony arrestees only.

The decision about who should be tested will likely be driven by availability of resources. A jurisdiction may decide to preserve its testing resources by using this information-gathering technique only for defendants charged with felonies.[1] The population targeted for testing, however, should not exceed the population for which interviews, investigations, and risk assessments are conducted.

A variety of recommendation schemes exist in pretrial services programs. Some are objective systems, using point scales or bail guidelines, in which the defendant's score or point total guides the recommendation. Some are strictly subjective, in which an experienced staff person makes a recommendation based on an examination of the information as a whole. Some schemes combine features of both.

Whatever scheme a program uses, test results should not be considered more or less important than other drug use information gathered, such as admission of current drug use, current drug charges, or prior drug convictions. All information about drug use is needed to accurately determine a defendant's drug history and should be weighted equally in the scheme. The demonstration programs that conduct pre-initial-appearance testing have integrated test result information into their recommendation schemes in different ways.

Washington, D.C. The D.C. Pretrial Services Agency uses a combination of objective and subjective criteria. The scheme addresses risks associated with both court appearance and community safety. For instance, the program takes into account suspected alcohol or drug abuse and suspected mental health problems. It also considers whether the defendant resides outside the area, has an unverified address, or has a prior history of failure to appear. A range of solutions, or recommended conditions of release, is listed to offset each identified risk. For example, if the defendant has a history of failure to appear in court, the options available to recommend as conditions for release include:

- Requiring that the defendant reside at a particular address while the case is pending.
- Placing the defendant into the third-party custody of a private individual, such as a relative.
- Requiring that the defendant report in person to the Pretrial Services Agency once a week.
- Placing the defendant into the third-party custody of an intensive supervision program.
- Requiring that the defendant report to the Pretrial Services Agency once a week in person and four times a week by telephone.

The staff person makes a subjective selection of the least restrictive conditions within the available range that will meet the appearance risks posed by the particular defendant. A supervisor reviews each recommendation before it is submitted to the court.

When the program began pre-initial-appearance drug testing in 1984, the test results were used solely as an additional means of determining suspected drug abuse. The risk category of "suspected drug use" was given no greater weight than existed previously. However, at the same time, drug testing was also begun as a supervision tool, making available an additional condition of release.

Maricopa County. The Pretrial Services Agency of Maricopa County uses a bail guideline approach

to assessing risks. The guideline scheme has a two-dimensional matrix. One dimension of the matrix lists a six-level charge severity index, and the second dimension lists four categories of pretrial risk. Defendants are categorized on each dimension, and the intersection of the two dimensions provides a specific range of release classifications to guide the judge. The types of release classifications available include release on recognizance, release on standard conditions, release on special conditions, and secured bond amounts.

Release on recognizance is recommended for defendants with low risk and low charge-severity scores. When released on standard conditions, these defendants can be required:

- Not to return to the scene of the crime.
- Not to initiate contact with the alleged victims, witnesses, or both.
- Not to possess any weapons.
- To continue to reside at the present address.
- To contact the probation officer.

Release on special conditions involves active supervision by the Pretrial Services Agency or a third party, such as a drug treatment program. The secured bond amounts range from a low of $685 to a high of $20,550, although the court may set bail outside this range. When introduced in 1988, drug testing became an additional special condition that could be imposed on defendants who tested positive prior to the initial appearance or had other indicators of drug use.

Milwaukee County. The Wisconsin Correctional Service (WCS), which operates pretrial services in Milwaukee County, also uses a bail guideline approach to assessing risks. A two-dimensional matrix system, similar to the one used in Maricopa County, is used. The matrix categorizes defendants into those who should be released with no conditions, those who should be released with the least restrictive conditions (minimum supervision by WCS), and those who should receive either the most restrictive conditions (maximum supervision by WCS) or post cash bail.

As in Maricopa County, the drug test result obtained before the initial appearance is not factored into the initial bail guideline calculation. If the defendant tests positive, a condition of drug testing is often added.

Prince George's County. Before the implementation of drug testing in 1988, the risk assessment scheme was straightforward. The program would not recommend release if:

- The pretrial services program was unable to verify the information provided by the defendant during the interview.
- The defendant had a history of three or more unexplained failures to appear.
- The defendant was charged with a dangerous or violent offense.
- The initial bail set at arrest by a commissioner was greater than $15,000.

A standard condition of release in every case was that the defendant report to the program once a week by telephone. Those defendants who admitted drug use during the pretrial interview were referred to the county health department for drug treatment. Electronic monitoring was available in a few special cases.

When drug testing was introduced, no greater weight was placed on drug use information than on any other factors. Instead of relying solely on self-reported use, however, the program used drug test results as an additional means of identifying drug users.

The pretrial program did, however, change two aspects of its risk assessment procedures. It abandoned the policies that withheld release recommendations for defendants charged with dangerous or violent offenses and defendants whose initial bail was more than $15,000.

Post-Initial-Appearance Testing

Two of the demonstration programs, Multnomah County and Pima County, began by testing arrestees before initial appearance. However, after 2 years, both programs delayed the initial drug test until after the court had decided on initial release or detention. In Multnomah County, for instance, program administrators concluded that procedures for testing before the initial appearance were not effective for several reasons.

The first related to the timing of the arrestees' release. The court delegated to the pretrial services program

the authority to release arrestees (except those charged with murder or treason) from jail without prior judicial review. Program staff are available at the jail 24 hours a day, 7 days a week, and they interview and investigate arrestees as they are being booked. Arrestees who are approved for release by program staff are released immediately but return to court the following workday for a judicial review of the program's release decision. Moreover, defendants not approved for release by the program are brought before the court for a review of that decision as well.

During the period in the program when specimens were collected prior to the initial hearing before a judicial officer, administrators struggled to staff the jail with specimen collectors from the local Treatment Alternatives to Street Crime (TASC) program. Having collectors on duty 24 hours a day, 7 days a week, proved to be expensive and not very cost-effective since, on several occasions, only a few arrestees would be booked during a particular shift. Moreover, specimen collection required that staff consist of one male (to witness specimen submission by male arrestees) and one female (for female arrestees), an inefficient use of staff time.

Second, it became apparent after several months of operation that the judges in the initial-appearance court were not making extensive use of the test results. In many cases in which the defendant had tested positive and the pretrial services program had recommended drug testing as a condition of release, the condition was still not imposed. Program administrators interviewed judges about this and determined that despite the judges' full support for the effort, the new drug test information was being lost in the hectic atmosphere of the arraignment court. To address this problem, the chief criminal judge issued a blanket order making participation in the drug testing program an automatic condition of release for defendants for whom there was some indication of drug use, unless the judge presiding at the initial appearance ruled otherwise.

The third reason why pre-initial-appearance testing was deemed ineffective was that in only 6 percent of the cases in which defendants were referred into the testing program was the positive drug test result the sole indicator of drug use. Other indicators of drug use included the current drug charge, a history of drug convictions, and admission of drug use by the defendant during the interview with pretrial service officials.

Taken together, these factors led to a decision to end pre-initial-appearance testing. Under the revised procedures, all the information collected in the interview, verification, and criminal history check—including information about drug use that is obtained from these sources, but excluding drug test results—is gathered and presented to the court with a risk assessment. The initial test does not take place until after the arrestee has been released and is conducted only if no other indicators of drug use are present.

A program that does adopt the post-initial-appearance testing approach must determine who among those released will be targeted for testing. In Multnomah County, any released defendants who are charged with felony offenses and for whom there are other indicators of drug use (such as self-report, history of drug offenses, and current charge) would have drug testing as a condition of release. Those for whom none of these indicators are present are asked to submit a specimen upon release. If the result is positive, the defendant is placed in drug testing as a condition of release. If the result is negative, the defendant has no testing requirement as a release condition.

In Pima County, officials used a "Drug Risk Assessment Scale," which attempted to identify defendants shown through previous research to have a high probability of testing positive. For defendants who tested above a specified level on the scale, the program recommended that a specimen be submitted before release and, if the result was positive, that participation in drug monitoring be a condition of release. Any defendant charged with a drug offense would automatically be recommended for drug monitoring.

Performance Measures

Program administrators should continually review how test results are being integrated into the risk assessment process. Particular emphasis should be placed on maintaining the traditional means of gathering drug use information: self-admission by the defendant, record of prior or current drug offenses, and reports from probation or parole officers. For instance, if the rate of admitted drug use by defendants has decreased since the introduction of drug testing, this may indicate that interviewers are placing less emphasis on obtaining a thorough interview becau

they know that the test exists as a backup. Any sign that program staff are placing less emphasis on investigating the traditional sources of obtaining drug use information should be rectified immediately.

Administrators can review a number of factors to measure the performance of drug testing as a risk assessment tool.

Pre-initial-appearance testing. To be useful in pre-initial-appearance risk assessment, the test results must be available to the court at the initial appearance. If the program is unable to collect specimens from a sufficient number of defendants before initial appearance, the goal of integrating drug test results into the initial release decision will not be achieved. Program administrators should keep monthly statistics on the percentage of cases in which test results were not available at the initial hearing. This figure should be broken down by:

- Percentage of cases in which defendants refused to submit a specimen.
- Percentage of cases in which a specimen was not collected for reasons other than defendant refusal, such as inability to approach the defendant before the start of court.
- Percentage of cases in which specimens were collected but not tested in time for the initial court hearing.

Program administrators may find that in the first few months of operation, as staff become accustomed to approaching defendants about submitting to drug testing and to delivering results in time for court, the percentage of cases for which results are available will be low. For example, the Multnomah County program initially collected specimens from only 40 percent of eligible defendants. The Maricopa County program initially experienced a 54-percent refusal rate and made available only 60 percent of collected test results in time for the initial court appearance. By gathering data on the reasons for the absence of results in the remaining cases, administrators can focus their efforts on where the problems lie. If larger percentages of defendants are refusing to submit specimens, then administrators should look at how staff are approaching defendants and explaining the purposes of the test. If over 10 percent of the target population are not being approached by program staff at all, the reasons for this should be explored as well.

Program administrators should determine if the testing program is slowing down the initial appearance hearing. If the court is being delayed because the results are not available, the court can pressure the program to speed up the process, or simply convene and conduct the initial hearings without the test results, thereby frustrating the goals of the program.

Program administrators should examine whether the court has been using the test results in setting conditions of release or detention. If judges are not ordering either drug testing or drug treatment as a condition of release for a significant number of defendants who have tested positive and been released, the results cannot be having an impact on judicial decisionmaking.

Post-initial-appearance testing. For testing to be useful in post-initial-appearance risk assessment, defendants must submit specimens upon release. Defendants may stand in court and promise to report immediately to the pretrial services program for the initial test. However, if they do not report, or if they do report but for some reason do not submit specimens, the second phase of the risk assessment has not been completed. Program administrators should keep monthly statistics on the percentage of cases in which defendants did not submit to the post-initial-appearance test, and they should review the procedures used to track those cases.

Summary of Major Points

- Traditionally, drug use information has been gathered through interviews with arrestees, contact with reference persons and probation or parole officers, and a review of the defendant's criminal history. Drug use information can also be obtained through drug testing, which provides an objective, scientific measurement of a defendant's drug use.
- Drug testing for risk assessment purposes can take place before the initial appearance in court or immediately after the initial appearance. If it takes place before, the test results can be incorporated with other information in making a recommendation to the court. If it takes place after the initial bond hearing, the purpose of the testing is to determine whether testing or treatment should be a condition of release.

- Program administrators should continually review how well results are being integrated into the risk assessment process.

Notes

1. For a discussion of the impact that the size of the target population has on resources, see *Estimating the Costs of Drug Testing for a Pretrial Services Program*, Washington, D.C.: Bureau of Justice Assistance, 1989. This document is available from the Bureau of Justice Assistance Clearinghouse at 1–800–688–4252 and the Pretrial Services Resource Center at 202–638–3080.

CHAPTER III.
INTEGRATING DRUG TESTING INTO THE SUPERVISED RELEASE PROCESS

In general, a pretrial supervised release program involves the monitoring by program staff of defendants who have been released on their promises to abide by certain conditions. The conditions should be related to risks—identified for each particular defendant—of failing to appear at scheduled court hearings and of presenting a danger to the community. The supervision of those conditions should be geared toward minimizing those risks. These same goals of minimizing identified risks should apply when integrating drug testing into a supervised release program.

Drug testing as part of a supervised release program will typically involve the following:

- Defendants will be required to report to submit a urine specimen on a periodic basis.
- Program staff will monitor compliance with the drug testing condition, noting the test results and whether defendants report as scheduled.
- Staff will counsel defendants who are testing positive or otherwise not complying and, using guidelines, will impose or recommend sanctions.
- Sanctions may include an increase in supervision levels, a referral to treatment, or notification to the court that the defendant has failed to comply with program requirements.

The degree of defendant supervision afforded by drug testing is different from that provided by any of the other types of conditions traditionally associated with pretrial supervision programs. To best understand how to take those differences into account when integrating drug testing into a pretrial supervision program, it may be helpful to review traditional supervision.

Traditional Conditions of Pretrial Release

The conditions set by the court and supervised by pretrial services agencies generally fall into four categories of conditions: status quo, restrictive, contact, and problem-oriented.

Status quo conditions. The defendant is required to maintain residence, employment, or school status. In many pretrial services programs, the status quo conditions are passively supervised, at best. Program staff may from time to time check to make sure that defendants have maintained their residence, employment, or school status. Often, a change in status may come to light only when defendants call attention to themselves by being rearrested or missing a court appearance. Even then, little action is taken if these types of conditions are violated. The court is not likely to revoke the release of a defendant simply for moving to a different residence or changing jobs.

Restrictive conditions. The defendant is required to remain in the jurisdiction or to stay away from the complainant or certain areas. Usually, restrictive conditions are also passively supervised. If defendants leave the jurisdiction or enter a restricted area, supervising staff may not find out. If the defendant approaches the complainant, this fact will remain unknown unless the complainant reports it. Although a violation of this condition is more likely to provoke a response from the court, instances are relatively rare.

Contact conditions. The defendant is required to report periodically by telephone or in person to the pretrial services or other supervising agency. Contact conditions can be supervised either passively or actively. In jurisdictions where the volume of defendants

required to report to the agency is higher than the agency can actively manage, or where the agency does not place high priority on the supervision of this condition, defendants who are delinquent in their reporting may go undetected. In these jurisdictions, the events that would trigger a detection of reporting delinquency are usually failure to appear in court or rearrest on a new charge. These events come too late for a court's response to have any meaningful effect.

Jurisdictions that actively supervise a contact condition know when defendants fail to report and take steps to bring them back into reporting compliance. When these efforts fail, the court is notified and the agency may recommend a hearing to determine whether release should be revoked. If defendants appear at that hearing, their very presence rebuts the argument that they present an appearance risk. Therefore, the court may be reluctant to impose sanctions.

Problem-oriented conditions. The defendant is required to enroll in substance abuse treatment or vocational counseling. Problem-oriented conditions are the most likely to be supervised actively. In actively supervising these conditions, program staff refer defendants to treatment or counseling centers and regularly check with officials of the centers on the status of those referred. Some supervised release programs merely refer defendants to these centers and assume that all is well unless the center reports otherwise.

Action by the court on violations of these types varies depending on the jurisdiction and judge, as well as on the condition involved. A violation of a drug treatment referral may be viewed as more serious than failure to report for a job counseling appointment.

Drug Testing as a Release Condition

Drug testing introduces a new feature to pretrial supervision—monitoring the use of illegal drugs by defendants on release. As noted, the status quo and restrictive conditions are not easily monitored. With a contact or a drug treatment condition, defendants must merely appear at a specified location a certain number of times per week. The rest of the time, their activities go unsupervised. With drug testing, however, defendants using drugs while on release and out of the view of supervising officials stand a better chance of being detected when they violate their release condition. Therefore, drug testing extends the reach of supervision beyond that provided by traditional forms of supervision.

This extended reach brings with it implications that program administrators should keep in mind when planning for integrating drug testing into supervised release programs. In jurisdictions that have adopted drug testing, judges have responded in unprecedented fashion to violations of the drug testing condition. Given this interest among the judges, programs in these jurisdictions have had to ensure that the resources were available to supervise the drug testing condition actively, to respond in a timely fashion to any infractions, and to alert the court when violations occurred.

Testing Results and Frequency

Other issues related to drug testing as a condition of release must be addressed in the planning stage. Those issues relate to the scheduling of testing appointments and the program's responses to instances of noncompliance. In scheduling defendants for drug monitoring appointments, two things need to be considered: the testing schedule and the frequency of testing.

Scheduling for a drug testing appointment differs from scheduling for a typical contact-related condition of release. A contact-related condition is usually imposed to make sure that defendants keep in touch periodically with court officials so that there is no confusion about the next court date. Programs therefore tend to provide latitude to defendants as to when to report. Defendants may be instructed to report in person once a week, but it may not matter to the program personnel which day of the week it is. In scheduling a drug testing appointment, however, such latitude cannot be granted, for each day a defendant could assess the likelihood of drug use being detected. If there were a likelihood of detection on that day, the defendant could simply wait until the next day to report.

Drug testing appointments can be set on a regular fixed schedule or on an irregular schedule.

Regular scheduling system. Under a system of regular scheduling, defendants know their next scheduled test date in advance because the appointment is on a fixed day or days each week, say a Wednesday. The defendant is advised of this on admission into the testing program and receives written notification as well. Each Wednesday when the defendant reports, he or she is given written notice of the date of the next appointment—the following Wednesday. A defendant missing an appointment is already on notice that the next test is scheduled for the following Wednesday.

A regular scheduling system makes it easier for defendants to keep track of their appointments and more difficult for them to use confusion about the date as an excuse for not reporting. It also enables defendants with jobs or other responsibilities to avoid scheduling conflicts. A regular scheduling system may also be easier for the program to administer. Since each defendant is assigned a fixed day or days each week to report, the staff can more easily track compliance.

The disadvantage of regular scheduling is that defendants can plan their drug use around their drug testing appointments.

Irregular scheduling system. Under an irregular scheduling system, the testing program devises procedures to make sure that the testing dates occur irregularly—so that defendants cannot anticipate the next test date—and to notify defendants when it is time to report for a test.

Various means can be used to establish an irregular testing schedule. Exhibit 3–1 is an example of an irregular system for defendants who are required to report once a week to submit a specimen. In this example, a defendant is assigned a color corresponding to the day of the week that he or she is enrolled in the testing program. A schedule can then be devised to determine each testing appointment, as shown below.

In this example, no color appears on the same day of the week over the 5-week period. Some programs opt to have the same color appear on the same day of the week in successive weeks so that defendants will not think that just because they were tested on Monday one week they will not be tested on Monday the next week. Other programs establish a random scheduling system in which the color code or other means of designating each defendant is randomly selected.

Notifying defendants of their next appointment with an irregular system is more cumbersome than with a regular system. Programs should decide how much notice to give defendants that a test is scheduled and how to provide that notice. Ideally, defendants should be instructed to report for testing within hours of the notification or before the end of that day. However, to give defendants some chance to make arrangements for their jobs, child care, or other factors, it may be necessary to provide notice the day before the actual test is scheduled.

Defendants can receive notification of the day of testing by two means. One places the burden of notification on the program, and the other places the burden on the defendants. In the first, program staff are responsible for calling all defendants who are due to report. Depending on the number of defendants who will be scheduled to report, this approach could be very time consuming for staff. In the second approach, defendants are typically required to call the program every day to see if their assigned color is scheduled. Placing the burden of daily calling on

Exhibit 3–1

Irregular Testing Schedule

Day of week	Week 1	Week 2	Week 3	Week 4	Week 5
Monday	red	yellow	blue	green	purple
Tuesday	yellow	blue	green	purple	red
Wednesday	purple	green	yellow	red	blue
Thursday	blue	red	purple	yellow	green
Friday	green	purple	red	blue	yellow

defendants may result in higher rates of noncompliance with the program, as many defendants will fail to call every day.

While an irregular testing system has the advantage of keeping defendants at greater risk of being detected if they use drugs, it is generally more difficult to administer than a regular system and also contributes to scheduling conflicts for defendants.

Frequency. Establishing the frequency for testing appointments is a policy decision to be made by program administrators with input from other system representatives. The frequency favored by the jurisdictions currently involved in pretrial drug testing is once a week. With the retention rate of most drugs of abuse averaging about 48 to 72 hours (see Chapter V, Testing of Urine Specimens, for a list of retention rates), it is true that testing once a week may allow some defendants to escape detection. When once-a-week testing is combined with an irregular schedule, this possibility is lessened. Still, weekly testing using either type of schedule will identify defendants with severe drug problems.

Testing twice a week will certainly be more effective, and three times a week virtually assures that any drug use will be detected as long as the appointments fall at appropriate intervals. This is difficult to manage with an irregular scheduling system. When testing more than once a week, the program must account for the fact that the same ingestion of a drug that led to a positive result on Monday could lead to a positive result on Wednesday. For this reason, testing more than three times a week is redundant.

The frequency of testing may be decided by the availability of testing resources. Having defendants report three times a week instead of once means that three times as many tests must be conducted. Staff and other resources must be sufficient to meet this demand.

Imposing Sanctions for Testing Violations

For each defendant who is scheduled to report for a drug testing appointment, one of six outcomes will occur. The defendant may:

- Fail to report.
- Be granted an excuse not to report.
- Report and refuse to submit a specimen.
- Report and be unable to submit a specimen.
- Report and test negative.
- Report and test positive.

The outcome for each defendant on each appointment must be accurately recorded and must be reviewed by staff to decide if the specific outcome warrants any action by the program. Technically, a violation of a drug testing condition occurs if the defendant:

- Tests positive for drug use.
- Fails to report for a testing appointment.
- Reports but refuses or is unable to provide a specimen.

Violations of a drug testing condition, and the responses of the program to the violations, present several difficult issues that must be addressed during planning. For instance, if the defendant reports for all scheduled testing appointments, and submits a specimen on each occasion, but the test result is always positive, is this a less serious infraction than if the defendant does not report at all?

The answer to this question involves making policy decisions after consulting with the judges, prosecutors, and defense attorneys (see Chapter I, Gaining Support From Criminal Justice System Representatives). The violation policy of the Milwaukee County program, which is similar to that used in the other demonstration jurisdictions, attempts to address the issue. As the Milwaukee County policy is designed (see exhibit 3–2 on the next page), failure to report is viewed as a more serious violation than reporting and testing positive. The status of defendants who continue to test positive is evaluated in the context of whether they are in active treatment. If they are, this mitigates the violation.

As shown in exhibit 3–2, sanctions against a defendant for violating release conditions can be designed to escalate, with several intervening steps in which there is an attempt to reestablish compliance, before a reconsideration of release by the court is

Exhibit 3–2

Milwaukee County Violation Policy

Defendant Violation	Program Response
First positive or no show	■ Notify court ■ Counsel defendant on obligation to comply with conditions
Second positive or no show	■ Notify court ■ Counsel defendant about treatment ■ Increase testing frequency to twice a week
Third positive	■ Notify court ■ Counsel defendant about treatment
Third no show	■ Notify court ■ Ask for bail review hearing
Fourth positive	■ Notify court ■ Request bail review hearing if defendant has refused treatment
Fourth no show	■ Notify court ■ Request bench warrant for defendant's arrest

sought. A policy of escalating sanctions is normally accompanied by a policy of de-escalating (reduced) sanctions. Defendants who, because of earlier lack of compliance, received more intensive reporting or testing requirements, can be moved back into the normal reporting schedule after a period of compliance with the more intensive requirements.

Notification to the court of a defendant's compliance with a drug testing condition need not be limited to instances of violations. Judges may find it useful to regularly receive full compliance reports on all defendants. For instance, the D.C. Pretrial Services Agency submits to the court a computer-generated report on compliance with the drug testing condition a day or two before each defendant's scheduled appearance. This allows the judges to respond to defendants who are in violation and gives encouragement to those who are doing well or at least making an effort to stop using drugs.

Program administrators should develop a policy of amending the conditions of release for defendants who are in full compliance with the testing condition. For instance, if the defendant reports for every appointment, tests negative each time, and is in compliance with all other release conditions, scaling back the frequency of his or her testing may be appropriate. Alternatively, a defendant in good compliance can be placed on an irregular testing schedule, with testing conducted once or twice a month.

Performance Measures

Program administrators have several means of evaluating the effectiveness of their procedures, beginning with a review of the compliance rate of defendants with drug testing requirements. It is not unusual for some defendants to fail to report for the intake appointment or miss testing appointments. If large percentages of defendants are failing to report for testing appointments, the reason may be related to the program's operation; the hours or the location may be inconvenient. Or the instructions given to defendants about their testing appointments or the consequences for failing to abide by release conditions may not be clear.

Program administrators should also check that the guidelines for handling noncompliance are being followed by staff, that the sanctions for violating conditions are being imposed in the timeframe specified by the guidelines, and that the court is being notified of alleged violations in a timely fashion. Periodic reviews of a sample of cases may be a helpful means of determining these things.

Mistakes by staff are inevitable, especially in the first several months of operation. It may not be unusual to encounter instances in which defendants were given the wrong date to appear for a testing appointment or where erroneous information was provided to the court. Program administrators should make clear to staff that any mistakes discovered should be reported immediately to the appropriate program supervisor. In addition to notifying the court if any misinformation was released, the supervisor can investigate and

analyze the mistake to determine whether a flaw in the procedures or a shortcoming in the training of staff was responsible, and to take corrective action accordingly.

Summary of Major Points

- Drug testing as a condition of supervised release is different from traditional types of release conditions. It offers a means of supervising the drug use of defendants while they are out of the view of supervising officials.
- Drug testing appointments can be set on a regular schedule with defendants advised of the next appointment in advance, or on an irregular schedule with defendants receiving very short notice to report for testing.
- Several options are available for setting the frequency of testing appointments.
- Monitoring a drug testing condition requires active supervision by the pretrial services program.
- Guidelines must be established and consistently followed for responding to violations of the testing condition.

Part Two: Operational Issues

CHAPTER IV. CHAIN OF CUSTODY

The term *chain of custody* encompasses procedures that govern:

- The collection, handling, storage, testing, and disposal of a urine specimen in a manner that ensures that the specimen is correctly matched to the person who was required to provide it and is not tampered with or substituted in any way.
- The documentation that these procedures have been carried out in each case to provide evidence of a correct match.

Strict adherence by staff to all chain of custody procedures is important for three reasons, all of which are related to quality control. First, it ensures that the person being tested does not tamper with the specimen. Given the subject's interests in producing a specimen that would test negative for drug use, various efforts at subterfuge may be employed. Second, it is necessary to establish that a particular result was obtained from the specimen provided by a particular defendant. Any breaks in the chain of custody can cast doubt on the result. Third, a regular review of the chain of custody documents by program supervisors can be an effective means of detecting early common errors by staff in areas such as specimen collection and handling.

Collection Facilities

The availability, location, and specifications of facilities used to collect specimens have chain of custody implications. Ideal facilities may not be available in a courthouse, jail, or other government or private building where the collection will be taking place. Moreover, given the expenses associated with installing plumbing and lavatory fixtures, it is often not possible to construct a collection facility in the most desirable location. Program administrators may therefore be forced to look elsewhere.

For incustody testing. When defendants in custody are being tested, the options for the choice of a collection facility will be limited. Clearly, a facility must be chosen that is within the perimeter of the custody environment. Even within that environment, the officials in charge of custody (sheriff's or corrections department) will have security concerns that may further limit the choice.

If arrestees are detained in one holding cell while they await transfer to the initial court hearing, there will most likely be lavatory facilities within that cell. From the standpoint of the custody officials, this probably would be the most convenient and secure location for collection to take place. However, from the standpoint of chain of custody, collection within a large (and usually crowded) holding cell is problematic. Staff would either have to enter the cell or stand outside and attempt to control the movement of other detainees to make sure that an unobstructed view of the person submitting the sample is maintained. Program administrators must work within these constraints to find a suitable location that allows for required observation.

For noncustody testing. Defendants appearing for monitoring appointments will be required to report to a specific location to check in and have their identification verified. Ideally, the collection facility should be located near the office where this check-in occurs; it would be an inefficient use of staff time to escort each defendant to a rest room in another part of the building. Moreover, the room in which collection takes place must be large enough to accommodate both the defendant and the witness and must afford the witness a vantage point to directly observe the defendant void the specimen.

Public rest rooms may meet both proximity and space criteria, as they are usually located near offices and are large enough to accommodate the witness, but they should not be used as collection facilities. In addition to the greater intrusion on the subject's privacy (and the potential legal challenges that may follow), the presence of others in a public rest room may distract the witness, thereby diminishing the

witness' ability to observe the voiding of the specimen. If it is absolutely necessary to use a public rest room, it should be closed to the public during the collection process.

Of course, concerns about chain of custody should not be the sole factor in determining the location of the collection facility. Selecting a facility that is not readily accessible to defendants, for instance, would make it difficult for defendants to appear for testing appointments.

Specimen Collection

Procedures must exist to verify the identity of the person presented as the subject to be tested. If defendants are being tested while they are in custody following arrest, procedures should already exist for establishing positive identification. Typically, once defendants are booked into the jail or lockup facility, a wristband is placed on them or a photograph is taken. If these or other means of identification are not available, staff should interview the defendant and check the information provided (date of birth or Social Security number, for instance) against official records before collecting a specimen.

Establishing the identity of defendants not in custody calls for caution. These defendants may have had the opportunity to enlist a surrogate to report in their place. However, identification can be established in several ways. Simply checking a driver's license or other photo identification should suffice. Since many defendants may not possess such identification, the program may wish to take its own picture of the defendant on admission to the program or obtain a copy of the photograph taken at booking, keeping the photo in the files for retrieval each time the defendant reports.

The D.C. Pretrial Services Agency uses computerized technology to capture the image of a defendant upon admission into the program and simply retrieves that image from the computer each time the defendant reports. However, the agency's training manual cautions staff not to rely exclusively on technology:

> Although we have a computerized picture-taking ability to minimize this possibility, no system is foolproof. Become familiar with the technology but do not let it become a substitute for your common sense. If you have suspicions, or if the picture does not look quite like the defendant, you can always politely probe a little by asking the defendant to provide additional data (date of birth or address) that may help you determine if it is in fact the defendant, or if a friend has been recruited to give a sample.

Once a defendant's identity has been confirmed, staff should prepare a label that will be attached to the specimen container once the specimen is collected. The labels can be preprinted, listing the information that should be recorded.

Exhibit 4–1

Sample Label

Specimen Label

Name _____

DOB _____ ID number _____

Date _____ Time _____

Remarks _____

_____ Witness _____

Defendant's signature

Typically, before escorting the defendant to the collection facility, staff should fill in the defendant's name and date of birth on the label. In many jurisdictions, persons arrested are assigned a unique identification number by the police department, jail, court, or pretrial services program. This number is also recorded on the label before collection. Some jurisdictions choose not to record the defendant's name on the label for confidentiality reasons, particularly if the specimen is sent to a laboratory for testing.

Program staff must take precautions to ensure that specimens submitted by defendants are not tampered with or substituted. Generally, these precautions involve having program staff observe the defendant void a specimen. The observation should be conducted by a witness of the same sex as the defendant.

For incustody testing. When observing an arrestee void a specimen while in custody following arrest, staff should consider that the arrestee did not know that he or she was about to be arrested and therefore lacked opportunity or motive to conceal a substitute specimen or adulterating chemicals. Moreover, the arrestee undoubtedly has been searched by arresting officials, and any devices that may have been present should have been detected. The witness may therefore need to observe the voiding only to the extent necessary to ensure that dilution with toilet water or soap does not occur. This can be accomplished without directly viewing private body parts.

For noncustody testing. A defendant reporting for a monitoring appointment is aware that he or she will be submitting a specimen and could, therefore, conceal a substitute sample or adulterating chemicals or other substances that could interfere with the test. Staff may therefore need to more directly observe the defendant void the specimen. The witness must be able to see the urine leave the defendant's body and enter the specimen container. This requires either physical presence in the rest room or outside viewing through a properly placed window.

Even with this level of observation, it can sometimes be difficult to determine if the defendant has substituted or tampered with the specimen. If the witness sees a suspicious hand motion or believes that the defendant has deposited a substitute specimen, the witness should respond as unintrusively as possible, usually by informing the defendant that the specimen will not be accepted and that another specimen will have to be provided.

Methods Employed To Tamper With or Substitute a Urine Specimen

Placing chemical substances under the fingernails and releasing them into the specimen during or immediately following the void.

Scooping water from the toilet to dilute the specimen.

Placing a pinhole in the bottom of the container so that the urine will leak out by the time it reaches the laboratory.

Concealing balloons or other devices under the arm with a tube leading to the genital area. The device may contain a substitute urine specimen or contaminating substances.

Specimen Handling and Storage

To establish the chain of custody of a urine specimen, documents must account for every individual who handles the specimen.

Labeling. A mistake made in labeling the specimen is difficult to correct even if all other chain of custody and testing procedures are exactly followed (e.g., the defendant is positively identified before submission, the test is conducted by the most skilled operator on staff, and confirmation is done by an independent laboratory using the most sophisticated technology available). If the wrong label is placed on a specimen at the point of submission, the wrong result will be attributed to the defendant. If the defendant contests the results, the chain of custody and testing documents will provide strong evidence to contradict the defendant. To prevent a challenge to the identity of the sample, several general rules should be observed:

- The witness should label, observe, and collect one specimen at a time, even in a large holding facility, and the labeling should take place at the beginning of the procedure, not at the end.
- The witness should reaffirm the identity of the defendant before labeling. This can be accomplished by asking the defendant to state his or her name and date of birth, checking the response against the information already recorded on the label.
- Once identity has been confirmed, the label should immediately be affixed to the side of the container. The label should never be placed on the top of the container because container caps can be switched.
- All writing on the label should be in indelible ink.

Daily log. Since the specimen container and the label attached to it will be discarded on completion of testing, a permanent record of the collection must be established. The record should take the form of a daily log of all specimens collected and should include the name, date of birth, and identifying number of each defendant; the date and time the specimen was

Exhibit 4–2

Sample Collection Witness Log

Collection Witness Log

Date _____

Page ____ of _____

Subject Name	DOB	ID Number	Witnessed by	Time	Comments

collected; and the name of the witness. An example of a collection witness log is provided above.

Transportation to the laboratory. The level of difficulty involved in transporting the collected specimen from the collection point to the laboratory depends on the distance between the two. If the specimen is collected at the laboratory or in an adjacent office, the procedures should be simple. Typically, the person who witnesses the collection carries the specimen to the designated location in the laboratory.

If the specimen is collected at a distant facility, however, it will be impractical to deliver each specimen as soon as it is submitted; storage will be required. Stored specimens must be kept in a secure setting to prevent access by unauthorized parties. Specimens stored overnight should be refrigerated to prevent possible decomposition of any drug metabolites. Couriers should be employed to transport specimens to the laboratory. For each shipment to the laboratory, records should show how many specimens are being transported, the name of the person acting as courier, the time the specimens left the collection site, the time they arrived at the laboratory, the name of the person at the laboratory receiving the specimen package, and a notation by that person about any specimens that sustained damage or other irregularities that might be evident. An example of a specimen transfer log is presented on the next page.

Testing and Disposal

The specimen to be tested must be transferred from the container in which it was collected to the receptacle in which it will be tested. Care must be taken to make sure that the specimen remains matched to the person who provided it, since numerous specimens are tested simultaneously. The position of the receptacle on the instrument used to test for drugs should be recorded on a log and matched with the defendant's name and other identifying information from the label.

Since the volume of urine required to conduct a test is very small, an amount of urine should remain in the collection container after the desired volume has been transferred to the testing receptacle. It is important that the urine remaining in the collection container be retained in the event that followup testing is required.

Exhibit 4–3

Sample Specimen Transfer Log

Specimen Transfer Log

Date _____

Page ____ of _____

Section A: To be completed by courier

Specimens collected at _____ (Name of collection facility)
Time left collection facility _____
Specimens delivered to _____ (Name of laboratory)
Time arrived at laboratory _____
Number of specimens transported _____

ID numbers of transferred specimens

_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Signature of courier _____

Section B: To be completed by laboratory official receiving specimens

Were all the specimens listed in Section A delivered with this shipment? Y / N
If no, which specimens were missing? _____ _____ _____ _____ _____
Were all specimens in acceptable condition? Y / N
If no, which specimens were not? _____ _____ _____ _____ _____
Comments: _____
_____
Laboratory official receiving specimens _____

(See Chapter V, Testing of Urine Specimens, for a discussion of followup testing requirements.)

The unused portion of the specimen should be stored in its original collection container in a refrigerator until it is determined whether a followup test is required. Any specimen requiring storage beyond 24 hours should be frozen. To prevent tampering with any stored specimens, the refrigerator and the room in which it is located should be locked when unattended. Distribution of keys should be restricted to authorized personnel.

The specimen can be discarded once it is determined that no followup test is required or after followup testing has been completed. The policies for the disposal of specimens must be clear to staff to prevent inadvertent disposal of a specimen that is awaiting followup testing.

Management Challenges Related to Chain of Custody

The importance of strict adherence to chain of custody procedures cannot be overstated. Failure to comply with procedures could have severe consequences for the defendant and the program. Given the unpleasantness of observing and handling urine specimens, program supervisors should be watchful for signs of low morale or burnout problems among the collection staff. Staff with these problems may not be as conscientious in following chain of custody procedures.

A regular review of chain of custody documents provides the administrator of the drug testing program with an effective means of monitoring the staff's compliance with chain of custody procedures. If signatures, dates, or other vital information are not properly recorded on the chain of custody forms, it is likely that the staff do not understand the chain of custody procedures and that retraining is necessary.

Yet there is one area within chain of custody that is less easily monitored. Program staff observe a defendant submitting a specimen, but there is no monitoring of the staff witness. If the observation by the witness is less direct than specified by the procedures, the defendant is not likely to bring this to the supervisor's attention, or if the witness does not label the specimen in accordance with procedures, the defendant is not likely to complain. The privacy of the interaction between the defendant and the staff witness offers an opportunity for the defendant to bribe the witness into accepting a substitute specimen. This, too may go undetected.

Example of a Break in Chain of Custody

As a defendant reports for a testing appointment, the staff person does not notice that two defendants due to report that day have the same name. The staff person, being very busy, neglects to ask the defendant for date of birth or other identifying information and simply records the information shown on the appointment log. The staff person inadvertently transfers the identifying information that belongs to the other defendant with the same name. The witness who then observes this defendant submitting the specimen is also very busy and fails to ask the defendant for date of birth before placing the label on the specimen. The result later obtained from this specimen will be wrongly attributed.

Preventive measures are probably the best way to address these problems. Applicants should be carefully screened to determine their conscientiousness, attention to detail, and personal integrity. Once hired, staff should receive extensive training on chain of custody procedures with an emphasis on the importance of following those procedures in every instance. Rotation of staff may help to prevent morale and burnout problems.

The ultimate test of the effectiveness of chain of custody procedures is their acceptance in court. Have there been any cases in which the court has refrained from imposing sanctions on an allegedly noncompliant defendant because of concerns about the chain of custody procedures used? If so, program officials should review the record from the court hearing and make any necessary adjustments to the procedures.

Summary of Major Points

- The facilities in which specimens are collected must meet certain requirements regarding privacy and security.
- Adherence by staff to chain of custody procedures is important to ensure that the person being tested does not tamper with the specimen, that documented evidence shows the particular result was obtained from the specimen provided by the defendant, and that program supervisors can detect, through a review of chain of custody documents, any problems in specimen collection and handling.
- Chain of custody procedures should include detailed instructions on how to identify the person being tested, observe the voiding of the specimen, label the specimen, complete a collection witness log, transport the specimen to the testing facility, and test and dispose of the specimen.

CHAPTER V.
TESTING OF URINE SPECIMENS

This section addresses the tasks involved in testing urine specimens for drugs of abuse. The first part presents some of the terminology encountered in drug testing. Included are terms related to the different methodologies for testing urine specimens for drugs, the technologies employed to conduct testing, the testing instruments, the interpretations that can be drawn from drug test results, and the types of facilities in which testing can be conducted. Next, factors that should be considered to help make decisions on the testing methodology, technology, testing instrument, and facility are presented, followed by a discussion of how to implement the decisions once they are made.[1]

Review of Drug Testing Terminology

Most program administrators will not have a background in the disciplines related to the testing of urine specimens, and they do not need to be completely familiar with the complexities involved in the testing of specimens. However, to make informed decisions, program administrators need to develop at least a basic understanding of drug testing technology. The information in this section is meant to provide that understanding, beginning with a review of some of the basic terminology encountered with drug testing.

Methodologies. The most commonly used testing methodologies fall into two categories: immunoassay and chromatography. Whereas it is important to have some knowledge of the scientific principles underlying these methods to conduct testing and interpret results, a general understanding should be sufficient for the purpose of setting up a pretrial drug testing program. If an explanation of the scientific principles is required, such as when a test result is being challenged in court, the explanation is better left to the experts.

Immunoassays use antibodies to detect the presence of drugs or their metabolites in the specimen. A metabolite is a breakdown product that results when enzymes in the body chemically alter a drug to facilitate its removal from the body. An *antibody* is a protein that reacts only with a specific substance, such as a drug, or a group of similar substances that it is designed to detect. The substance which the antibody reacts to is an *antigen*. A tag—a substance that can be identified and measured after the antibody and antigen react—is attached to a sample of the drug being tested. The drug containing the tag is called the tagged antigen. The tagged antigen, the urine possibly containing the drug in question (*untagged antigen*), and antibodies that react specifically against the drug are mixed together, and the tagged and untagged antigens compete to react with the antibody. The remaining unused tag is considered an indicator of the presence or absence of drugs.

Chromatography involves separating substances in a sample by extracting them or causing them to attach to some type of material or particle. The separated substances are then identified and measured.

Technologies. The three technologies that utilize the immunoassays most commonly used in criminal justice settings are the *Enzyme Multiplied Immunoassay Technique* (EMIT™),[2] the *Fluorescence Polarization Immunoassay* (FPIA),[3] and the *Radioimmunoassay* (RIA).[4] Chromatography technologies in use include *Gas Chromatography* (GC) and *Gas Chromatography/Mass Spectrometry* (GC/MS).

Another commonly used, chromatography-based technology is *thin-layer chromatography* (TLC). However, a study comparing various technologies found that TLC was poor in identifying drug users. Specifically, TLC identified only about 8 percent of the positive opiate specimens, 11 percent of the positive cocaine specimens, 19 percent of the positive phencyclidine (PCP) specimens, 48 percent of the positive marijuana specimens, and 12 percent of the positive amphetamine specimens. This led the report's authors to conclude the following:

> Standard thin-layer chromatography was found to be seriously deficient in detecting the five substances examined in this study. Therefore,

> TLC is unlikely to be useful for screening or confirming urine specimens for illegal drug use within criminal justice populations.[5]

Given these findings, this monograph does not consider TLC a suitable testing technology.

Immunoassay technologies are the most suitable for use in criminal justice settings. However, RIA is not suited for onsite testing since the procedure uses radioactive materials that can be handled only by specially trained, licensed technicians and laboratories. Program administrators should contact the manufacturer of each technology for a list of the testing instruments that use a specific technology.

Interpretation of results. Immunoassays have moderate to good *sensitivity* and can detect small amounts of a drug in urine. However, *specificity*—the ability to distinguish a single chemical component from a closely related or *cross-reacting* component—depends on the procedure used and the drug being detected. While immunoassays are designed to identify specific drugs or drug metabolites, the chemical reactions that occur during the test may make it difficult to distinguish a specific drug from other substances, such as prescription drugs with similar chemical properties. As a result, *false positives*—an indication of the presence of a drug when in fact the drug is not present—can occur. Given this possibility, manufacturers of immunoassays, as well as toxicologists, recommend a followup test, or *confirmation*, using a method that is more specific to a particular drug or its byproducts, such as a chromatography test.[6]

True positive and *true negative* results are considered to be accurate. *Accuracy* refers to the ability of the test to obtain the correct result. To establish the accuracy of each result, however, followup testing on each positive result is required. As noted earlier, manufacturers of immunoassay technologies and toxicologists recommend that positive results be confirmed using an analytically different technology, such as chromatography. On the other hand, several courts that have examined the issue in various criminal justice settings have not required confirmation. Many of these courts have accepted *retesting* of positive specimens a second time using the same technology.[7]

The interpretation of drug test results using an immunoassay technology should be straightforward; the result is either *positive* or *negative*. These two terms

Exhibit 5–1

Interpretation of Results

Test Result	Drug Present In Specimen	Drug Not Present In Specimen
Positive	True Positive	False Positive
Negative	False Negative	True Negative

may seem very simple, yet they are often used incorrectly. If a result is positive, it means that a drug or its metabolite (or a closely related, cross-reacting compound) was detected above the test's *cutoff level*, the value that serves as an administrative breakpoint for labeling a specimen positive or negative. A positive result does not measure how much of the drug was present, the last time it was used, or the frequency with which it was used. A positive result is not, by itself, an indicator of impairment.

A negative result does not necessarily mean that the subject is not a drug user. It only indicates that no substance for which a test was run was detected in the specimen above the test's cutoff level.[8] The subject may have used a drug that was not part of the screen of tests. The drug or its metabolite may have passed through the subject's system before submission. Perhaps the subject was even able to submit a surrogate specimen.

For these reasons, drug test results should be discussed in terms of the *specimen* testing positive or negative, not the subject being a drug user or a nonuser. In short, a urine test is not an emphatic, absolute measure of whether a person is or is not a user of illegal drugs. However, many regard it as such, and program administrators should correct such misunderstandings whenever they arise.

Testing facility. In setting up a pretrial drug testing program, the testing function can be performed either in-house by the pretrial services program or by contract with an outside laboratory.

With in-house testing, a facility is set up within the pretrial services program. The pretrial program is responsible for purchasing testing instruments and supplies, hiring staff, training staff (or arranging for their training by the manufacturers of the testing instruments), collecting the specimens, conducting the

tests, and reporting the results. The actual facility is typically located in the jail or at the courthouse, or in proximity to either.

With a contract laboratory, on the other hand, the pretrial services program contracts with a laboratory to conduct the testing. The laboratory is responsible for having the testing instruments and supplies available. The laboratory is also responsible for hiring and training staff or assigning existing staff to the contract. The testing is usually conducted on the laboratory premises.[9] The results of the tests are reported directly to the pretrial services program for proper dissemination.

Quality control. *Quality control* refers to procedures put in place to monitor the operations of the laboratory. Quality control procedures should be both internal—that is, monitored by supervisory staff—and external. External quality control involves *proficiency testing*, that is, comparing the performance and operations of a drug testing laboratory with those of other laboratories.

There are two types of proficiency testing—open and blind. With *open proficiency testing*, a number of specimens are sent to the laboratory by a sponsoring group on a periodic basis. The laboratory is aware that these are proficiency testing specimens but is not aware of what, if any, substances they may contain. The laboratory tests the specimens and reports the results to the sponsoring group. The results are then compared to results submitted by other laboratories. The laboratory is advised by the sponsoring group how its performance compared with that of other laboratories.

Blind proficiency testing is identical to open proficiency testing in all aspects, except that the specimens arrive at the laboratory with no indication that they are proficiency testing specimens. Therefore, laboratory technicians are unaware that the performance of the laboratory is being measured.

Exhibit 5–2

Approximate Duration of Detectability of Selected Drugs in Urine

Drugs or their metabolites can be detected in the urine only for a limited period of time after the drug's last use. Listed below are typical retention times for a variety of drugs.

Drug or Metabolite	Duration of Detectability
Amphetamines/methamphetamine	48 hours
Barbiturates	
Short-acting	24 hours
Intermediate-acting	48 to 72 hours
Long-acting	7 days or more
Benzodiazepines	3 days (therapeutic dose)
Cannabinoids (marijuana)	
Single use	3 days
Moderate use (4 times per week)	4 days
Heavy use (daily)	10 days
Chronic heavy use	21 to 27 days
Cocaine metabolites	2 to 3 days
Opiates	48 hours
Phencyclidine (PCP)	8 days (approximate)

Source: Adapted from the *Journal of the American Medical Association's Council on Scientific Affairs*, 1987, p. 3112.

Choosing a Technology

The pretrial drug testing demonstration programs all used technologies based on the immunoassay methodology. The immunoassays have features that make them attractive to criminal justice programs. They can be run on instruments that test a high volume of specimens quickly, and the level of expertise required by operators of immunoassay-based instruments is much less than that required for most chromatography-based instruments.

The technologies available for detecting drugs in urine specimens provide a range of options for pretrial program administrators.[10] In choosing among the options, two factors should be considered.

Acceptance in the scientific community. The most important factor to be considered when selecting drug testing technology is whether it has gained acceptance in the scientific community. Do those who are most qualified to make such determinations, in this case toxicologists, view the technology as a reliable means of detecting the presence of drugs in a specimen? In discussions with manufacturers of these technologies, therefore, program administrators should ask to see evidence of scientific acceptance.

Admissibility of test results in the court. Since drug test results are intended for use by the courts, the judgment of whether results obtained from a certain technology are admissible in court proceedings lies with the court. In making such judgments, the courts determine whether the level of acceptance of the technology within the scientific community is sufficient to allow admissibility. Program administrators should review cases in which the admissibility of test results obtained from technologies under consideration were challenged in court.

Choosing a Testing Instrument

Once the pretrial service program has determined that the technology has been accepted by the scientific community and the courts, program administrators can look at the variety of testing instruments that use scientifically accepted technologies. The instruments offer different features to meet a variety of needs.

Turnaround time. The amount of time it takes to obtain the result from a defendant's specimen can be very important to a pretrial services program. If the program is using test results in formulating recommendations to the court at the initial appearance, the results must be available before that appearance. Even when using the results in the supervision phase, rapid turnaround time is important, as users should be promptly confronted with their results. Some testing instruments are designed to produce results very rapidly. Others may take more time.

Volume of testing. Some available testing instruments are better at accommodating a high volume of specimens, and others operate more efficiently with a low volume. The program may be required to produce results on a high volume of specimens in rapid fashion. If that is the case, there are systems available to accomplish this.

Availability and quality of training. If the pretrial services program contracts with a laboratory to perform testing functions, the administrator need not be as concerned with the training that is made available by the vendor of the instrument. The laboratory itself will be responsible for making sure that operators of testing instruments have received the proper training. If testing is to be conducted in-house, however, the availability and quality of training offered by the vendor is very important. A vendor that does not provide training should not be considered.

Costs. Vendors of testing instruments may offer options to lease or purchase the instrument. Program administrators should examine the terms of both lease and purchase agreements and determine which option best meets their needs.

Vendors may also offer pricing packages that reduce costs. For instance, one vendor may offer the testing system at no cost if the program commits to purchasing a determined amount of supplies. A competing vendor may offer the supplies at no cost if the system is purchased. However, the price of the various instruments should not be the main consideration in making a selection. If the least expensive instrument cannot meet the turnaround time and volume needs of the program, or is based on technology that has not gained acceptance in the scientific community, then it would be the wrong choice.

Program administrators should visit other criminal justice drug testing programs, clinical laboratories,

hospitals, or other institutions that use the testing instruments under consideration. It is helpful to see the instrument in operation and to question the operators of the system about their level of satisfaction.

Choosing a Testing Facility

The decision whether to implement in-house testing or to contract with an external laboratory may be one of the most difficult faced by a program administrator. The first step in deciding whether to test with an inhouse facility or to contract for testing is to look at several factors and determine whether both approaches remain viable options. If so, the advantages and disadvantages of each approach can be assessed.

Existence of State or local regulations governing testing facilities. Many jurisdictions have regulations that require laboratories to meet specified performance standards. Some require licensing or certification. In some jurisdictions, these regulations apply only to laboratories engaged in clinical testing; in others they may extend to all facilities that test specimens—including those that are set up in criminal justice agencies. Program administrators should identify existing regulations.[11]

Availability of an external laboratory. Program administrators should determine whether there are laboratories in the area that meet applicable regulatory requirements and that are willing to consider contracting with the pretrial services program. The Yellow Pages of the telephone book, under the heading of "Laboratories/Medical," should have a listing of laboratories that test for drugs. These laboratories should be contacted.

Local programs may exist that are not necessarily medical laboratories but currently provide testing services for other divisions of the criminal justice system. For instance, in many jurisdictions TASC programs perform this service for probationers, parolees, and the like.[12] Other criminal justice system representatives should therefore be consulted to see if there are programs that test criminal justice clients.

Availability of suitable space to locate in-house facility. Difficulties are often encountered in trying to set up an in-house testing facility in the jail, courthouse, or any other public building. Space of any kind can be difficult to secure in such a building. Space that meets or can be renovated to meet the requirements of a testing facility may not be available.

The area housing a testing facility must be secure against unauthorized access and be large enough to accommodate the testing instrument to be used. The instrument may require special plumbing or electrical hookups; therefore, any such modifications to the space should be anticipated. Since testing supplies and chemicals can be affected by temperatures above or below a room temperature range of 68 to 77 degrees Fahrenheit, a room that is not climate controlled would not be suitable.

It is convenient, although not necessary, if the area where defendants report for testing, and where they actually submit specimens, is adjacent to the testing facility. This simplifies chain of custody procedures (see Chapter IV, Chain of Custody).

Availability of staff for in-house laboratory. The pretrial services agency's personnel who are assigned or hired to operate the testing facility require specialized knowledge beyond that normally required to complete traditional pretrial services functions. Program administrators are responsible for recruiting, hiring, training, and supervising these staff members. Some administrators may conclude that these responsibilities are beyond what they want to be involved with, and may therefore select a contract laboratory.

Turnaround time. An efficiently managed in-house testing facility, with the appropriate testing instrument, should be able to meet turnaround time requirements. A contract laboratory may be able to meet the requirements as well. Once a turnaround time is established, program administrators can check with available laboratories to see which ones can meet the established time.

Costs. Different cost factors come into play if a contracted laboratory is used instead of an in-house testing facility. If testing functions are contracted out to a laboratory, the pretrial program is not responsible for purchasing instruments and supplies, hiring testing staff, and making renovations to a testing facility. However, the pretrial program is paying the laboratory for the use of instruments, supplies, staff, and other general costs associated with the laboratory's overhead.

Chain of custody concerns. Chapter IV describes acceptable chain of custody procedures. Chain of custody might be simpler to protect in an in-house facility, especially if the facility is located near the area where the specimens are collected. However, procedures can be developed for transporting specimens from the collection point to the laboratory. Plans under each option should be drawn up and compared.

Comparative Advantages of In-House and Contracted Facilities

Once factors regarding selection have been examined, program administrators must determine whether both approaches remain viable options. Perhaps there are no laboratories available that meet the program's turnaround time needs. Maybe there is no space suitable for an in-house facility. Ideally, both options will remain open, and if so, program administrators should then weigh the advantages and disadvantages of each. Given the differences among jurisdictions, each listed advantage may not hold true in every instance in every jurisdiction.

Advantages of an in-house facility. Generally, an in-house facility should be able to process the testing of specimens more rapidly than an outside laboratory. This is especially true when the testing facility is located near the collection site and when the facility is responsible for testing only specimens collected from the pretrial population. A contract laboratory would no doubt be providing results to other clients, and this could slow down the processing of the specimens for the pretrial program.

Chain of custody is simplified if the specimens do not leave the building in which they were collected. It is also simplified if custody of the specimens is not transferred from the pretrial program to the laboratory. With the pretrial program having sole custody of a specimen, program administrators can be more confident that chain of custody procedures are not compromised. Once a specimen leaves the custody of the pretrial program, the program loses some control over how that specimen is handled.

An in-house facility may also provide the pretrial program with greater confidence about the release of information. Since all test results are under the sole control of the pretrial services program until they are disseminated to appropriate officials, there is less danger of an inadvertent release to an unauthorized party.

Advantages of a contract laboratory. The contract laboratory will likely be staffed by trained technicians with experience in testing specimens. The laboratory is likely to have a staff toxicologist supervising the technicians. This toxicologist may be useful for testifying in court, if necessary, on the laboratory procedures used to obtain a test result.

A laboratory that has been in business for some time will have established a track record of performance. Program administrators can interview former or current clients of the laboratory to gain their impressions of the services provided by the laboratory. Program administrators can tour the laboratory, inspecting the facility and checking procedures.

A contract laboratory, especially a large one, is likely to have the resources to handle exigencies, such as instrument failure or staff turnover. An in-house facility that has purchased one testing instrument may be in a temporary bind if the instrument breaks down. Likewise, an in-house facility with only two trained operators may be hurt if one leaves.

Implementing Testing in an In-House Facility

The tasks involved in setting up an in-house testing facility involve completing an agreement with the vendor of the selected testing instrument, finalizing any necessary renovations to the selected space, ordering the testing system, hiring and training staff, purchasing the requisite supplies, setting up procedures for confirmation of positive results, and establishing quality control procedures.

Making the agreement with the vendor. Before placing the order for the testing instrument, program administrators should make sure that the terms of the agreement with the vendor are clear. If the instrument is purchased, the administrator should review the warranty with the vendor.

Many vendors offer maintenance contracts after the warranty period expires. These contracts can run into the thousands of dollars. Since they are not required

Exhibit 5–3

Advantages and Disadvantages of In-House Versus Contract Laboratory

Type of Laboratory	Advantages	Disadvantages
In-house	■ More rapid turnaround of results ■ Greater control over chain of custody ■ Greater control over release of information	■ Less experienced staff ■ Starting from scratch ■ Fewer resources
Contract	■ Highly trained staff ■ Record of performance ■ Greater resources	■ Slower turnaround time for results ■ Less control over chain of custody ■ Less control over release of information

during the first year of operation, or for as long as the warranty is in effect, the program may be faced with an unexpected bill when the warranty expires. Program administrators should be aware of this at the outset and should discuss with the vendors at the point of purchase the costs associated with maintenance contracts.

The instrument used to test urine specimens, like any other equipment, is subject to occasional failure. The problem can often be resolved by program staff if they obtain telephone instructions from technical representatives of the instrument's manufacturer. In other instances, however, an onsite visit by a technical representative may be required. Whether the instrument is purchased or leased, program administrators should ensure that an agreement is reached as to the response time for a service call. If the instrument cannot be fixed onsite and must be shipped out for repair, there should also be an agreement that the manufacturer will promptly provide a substitute instrument at no additional cost.

To ensure quality control, the protocol for the operation of testing instruments requires that periodic maintenance checks be conducted by trained technicians provided by the instrument's manufacturer. Program administrators should make sure that the frequency of these checks is in compliance with established protocol and that the frequency is recorded as part of the written agreement.

The availability of training by the manufacturer should also be addressed in the agreement. As a new program is starting, all staff who will be responsible for testing specimens must receive training. As turnover occurs, new staff should have ready access to training. Several manufacturers operate training centers that are continuously in session at their headquarters. Others offer periodic regional training sessions. Some of these training sessions are designed primarily for clinical technicians and do not focus specifically on testing urine to detect drugs. Therefore, program administrators must make certain that the manufacturer will provide the training that will meet program needs.

Renovating the facility. The vendor of the selected testing instrument should provide information on any special electrical, plumbing, or ventilation requirements of the instrument. Some vendors will even provide engineers to inspect the space and note any changes that will be required.

If the office space that will be used as the testing facility will require extensive renovations, program administrators should attend to this task next. It may be necessary to solicit bids for contracts for the construction work. This alone could consume several months. Once the contractors are selected, program administrators should meet with them to make sure that all the needs of the facility are understood. Program administrators should request a schedule for the completion of the work so that the completion of other tasks can be planned accordingly.

Ordering the testing instrument. Once the order has been placed, the vendor of the selected testing

instrument should provide a schedule for the delivery and installation of the instrument. Installation should be timed to occur after all renovations have been completed.

Hiring and training staff. Since the positions to be filled did not exist previously, staffing a new in-house pretrial drug testing program will require program administrators to develop job descriptions and job classifications. In jurisdictions where any new job descriptions and classifications must be processed and approved by county personnel departments, this could be a time-consuming task.

The vendor of the testing instrument should have a training program available for staff. Administrators should schedule training sessions for new staff as soon as possible. (See Chapter VII, Staffing, for a discussion of the issues surrounding staff recruiting, hiring, and training.)

Implementing quality control procedures. Effective quality control procedures involve compliance with previously established written protocols governing all aspects of the testing process, including chain of custody and the actual testing of the specimen. (Quality control procedures for chain of custody are described at length in Chapter IV, Chain of Custody.)

The manufacturer of the testing instrument should make available a list of quality control procedures to ensure the accurate and efficient operation of the instrument. The manufacturer of the reagents and other supplies used to conduct the test should also provide quality control procedures. All protocols and procedures for the maintenance and operation of the testing system, as well as the storage, preparation, and use of reagents and other supplies, must be observed in exact accordance with the manufacturer's instructions.

At a minimum, a system of quality control requires keeping complete records of all repairs and maintenance checks on the testing system, whether daily, weekly, or monthly, including the name of the person performing the work. Most testing instruments currently in use generate a hardcopy of the test results; these documents must also be maintained.

Program administrators should arrange to participate in at least one proficiency testing program. The National Institute on Drug Abuse of the U.S. Department of Health and Human Services (DHHS) maintains a list of proficiency testing service providers that have met the Department's certification criteria. The proficiency testing provider chosen should have achieved DHHS certification. Participation in proficiency testing should cost less than $1,000 a year.

If an incorrect result is reported to the proficiency testing service provider, administrators should investigate the reasons for the incorrect result and prepare a report for their files on the results of the investigation and corrective actions taken. Records of proficiency testing results must also be kept on file.

Implementing confirmation procedures. Some potential issues related to followup testing requirements may arise during the planning process, and program administrators should be aware of those issues. Manufacturers of immunoassays and toxicologists call for confirmation of all positive results obtained from immunoassays on a second, analytically different technology, particularly when the person tested may suffer negative consequences as a result. Due to the inability of immunoassays to distinguish between some substances that share similar chemical structures, a more specific confirmation test is required to accomplish the distinction. Scientists consider the GC/MS testing system to be the most reliable means of confirmation.[13]

The costs associated with confirmation by GC/MS, however, can be very high, ranging from $25 to $100 for each confirmation test.[14] If each positive result is confirmed by GC/MS, a pretrial services program with a high volume of testing and a large number of positive results may face operating costs two to three times greater than if no confirmation takes place.

As noted earlier, another less expensive option that has been approved by several courts is retesting specimens using the same technology.

Options may be available to program administrators for developing procedures for followup testing on positive specimens. For instance, the program may opt to confirm by GC/MS only those results that are disputed by defendants or those that will lead to court action.

Since confirmation of a positive result may require testing on a different methodology than that used in the initial screen, it is generally more practical to

contract with a laboratory for confirmation. An in-house testing facility is not likely to have on hand instruments utilizing a different methodology. Also, the skills required to conduct confirmation on the most preferable technology—GC/MS—are likely to be well beyond the expertise available at an in-house pretrial services drug testing facility.

Implementing Testing in a Contracted Laboratory

The tasks involved in contracting with a laboratory for testing will depend on whether the program is required to issue a Request for Proposals (RFP) to eligible laboratories and then select the laboratory after a competitive process. If this is a requirement, the program has to develop the RFP, review the proposals, and make a selection. Once a selection is made, whether through a competitive process or not, the pretrial services program must negotiate the terms of the agreement with the selected laboratory.

Developing a Request for Proposals. Before the RFP is written, program administrators should determine the selected laboratory's responsibilities. Clearly, the laboratory will be responsible for the actual testing of collected specimens. The collection of the specimens, however, can be the responsibility of either the pretrial program or the laboratory. If the pretrial program retains responsibility for the collection, transportation of the specimens can be left to the pretrial program or the laboratory.

Determining who will be responsible for the collection and transportation of specimens to the laboratory is a matter of individual choice for each program administrator. Some may want to turn over all testing-related responsibilities to the contracted laboratory because of staff resistance to handling urine specimens or because the administrator believes laboratory staff will carry out chain of custody more effectively.

On the other hand, some program administrators may want to retain the control provided through in-house collection and transportation. Also, program administrators may believe that defendants who have contact with the program staff collecting the specimens may comply better with testing. Indeed, in Pima County, officials first arranged that the laboratory collect specimens for both the pre-initial-appearance test and the supervision tests. After a period, procedures were changed so that pretrial program staff collected specimens, resulting in higher rates of collection. Similar results were obtained in Multnomah County when pretrial program staff took over responsibility for specimen collection.

Once the exact functions are decided and defined in the RFP, program administrators can describe the requirements of the program, such as turnaround time, expected volume, number of drugs to be screened, cutoff levels, and followup testing procedures. Based on this information, applicants should be asked to submit a budget with the proposal.

The RFP should also ask applicants to provide the following information:

- The testing methods, technologies, and instruments available for both screening and confirmation testing. Administrators may wish to specify in the RFP which testing technologies and instruments must be used by the laboratory.
- The chain of custody procedures from the point of collection and transportation (unless the pretrial program will handle these) to the point of testing and disposal of specimens.
- Proof of compliance with applicable licensing or certification requirements.
- Assurances that the laboratory follows the manufacturer's protocol for testing urine samples.
- The quality control procedures the laboratory uses.
- The credentials of staff (resumes should be included with proposals).
- The availability of staff to testify in court at violation hearings.
- A list of references of past or current clients, particularly of those involved in drug testing for the criminal justice system.

Reviewing applications. This should be a two-step process. The first step should be to read each proposal with the following in mind:

- Does the applicant address each question?
- Does the applicant meet any existing licensing or certification requirements?

- Has the technology used by the laboratory been accepted by the scientific community?
- Can the laboratory meet the needs of the program?
- Are the chain of custody procedures thorough?

The next step should be to contact the references and then conduct an onsite inspection of applicants still under consideration. During the inspection of a laboratory, administrators should:

- Verify the accuracy of information presented in the proposal.
- Conduct a walk-through of chain of custody procedures, having a laboratory official explain each step in the chain of custody process during the walk-through and check entries on chain of custody logs. (Review Chapter IV, Chain of Custody, before inspection.)
- Check the laboratory's procedures to protect the security of testing instruments, stored specimens, supplies, and records and determine who has access to restricted areas.
- Ask to see the laboratory's results from proficiency testing programs, being suspicious if proficiency test results cannot be produced immediately.
- Ask to see evidence of the laboratory's certification or license if required.
- Check the laboratory's procedures to ensure that it follows manufacturers' protocols for testing urine samples.

Selecting a laboratory. Program administrators should review the information provided in the proposals and collected during the inspections, then select the laboratory that best meets the requirements of the program.

Many jurisdictions may require selection of the lowest bidder in any government contract. In selecting a laboratory to conduct drug testing, however, the selection of the lowest bidder solely on the basis of the bid may actually result in greater long-term costs. If the reliability of the results obtained from the selected laboratory cannot be demonstrated in court, the program may become involved in costly litigation.

One toxicologist has published a sample laboratory selection score sheet to aid in an objective assessment of the applicant laboratories (see exhibit 5–4 on the next page). The use of such an instrument may make it possible to waive requirements for the selection of the lowest bidder.

Negotiating terms of the contract with the selected laboratory. Once the laboratory has been selected, terms of the contract with the laboratory must be negotiated and made final. The contract should address the turnaround time for the reporting of results, the drugs for which the laboratory will test, and the procedures for followup testing of positive specimens.

The contract should also specify the pricing arrangement. Two arrangements are available: cost-per-test and fixed-price. With a cost-per-test arrangement, the pretrial program pays the laboratory the specified amount for each test conducted. Typically, this means that the laboratory bills the pretrial services program at the end of each month after the number of tests for the month have been counted. With a fixed-price arrangement, the pretrial program pays the laboratory a set fee regardless of the number of tests conducted. The fee is calculated by estimating the expected volume of tests to be conducted.

With a cost-per-test arrangement, the pretrial services program pays only for tests that are actually conducted. With a fixed-price arrangement, the fee paid may not reflect the number of tests performed. If the volume was underestimated, the pretrial services program will pay for tests that were not done. If the volume was overestimated, the laboratory will not be compensated for the work completed.

Despite the uncertainty involved with the fixed-priced arrangement, both the pretrial services program and the laboratory may prefer it, for it permits them to develop budgets using the agreed-upon amount.

Program administrators should make sure that provisions of the contract allow for:

- Periodic and unannounced inspections of the laboratory by pretrial program officials and other technical experts chosen by staff.
- Assurances that the laboratory will follow the instrument manufacturer's protocol for specimen testing.

Exhibit 5–4

Sample Laboratory Inspection Sheet

Score Sheet
Drug Screening—Laboratory Selection

Laboratory _____ **Final Score** _____

Quality of services (60 points)

- Test methods (20 points) (Consider sensitivity, established reliability) — Score____
  - Screening: _____
  - Confirmation: _____
- Internal chain of custody (10 points) (Consider if description is adequate, methods of identifying samples, recordkeeping) — Score____
- Quality assurance program (10 points) (Consider use of standards, internal blind QC, certification of standards) — Score____
- Turnaround times (5 points) (Consider how results are reported, timeliness) — Score____
- Specimen pickup, shipping, provision for frozen storage (10 points) — Score____
- Supplies (5 points) (Consider form design, labeling security of bottles and kits, instructions for use) — Score____

Services Total Score_____

Personnel (30 points)

- Laboratory director/manager (15 points) (Consider who will provide expert testimony) — Score____
- Management staff (10 points) — Score____
- Technical staff (5 points) — Score____

Personnel Total Score _____

Experience (10 points)

- Current clients (5 points) — Score____
- Court/arbitration experience (5 points) — Score____

Experience Total Score _____

Source: Robert E. Willette, "Choosing a Laboratory," in *Urine Testing for Drugs of Abuse*, National Institute on Drug Abuse, Research Monograph 73, 1986, p. 13–19.

Performance Measures

Whether the testing is conducted with an in-house facility or by contract with an outside laboratory, several areas should be examined to measure performance:

- Are the test results being provided within the timeframe required by the program and the court?
- Are laboratory staff following testing procedures in all instances?
- Are quality control measures being implemented?
- Do these measures point to any problems in the laboratory's operations?
- Have any court challenges to the accuracy of the testing system, the procedures employed by the laboratory for testing, or the qualifications of the technicians performing the tests been successful?

Summary of Major Points

- To make informed decisions, program administrators should gain at least a basic knowledge of the technical aspects of testing urine specimens for drugs of abuse.
- Several technologies are available for testing of specimens. The most important factor to consider in selecting a technology is whether it has gained acceptance in the scientific community.
- A variety of testing instruments that employ these technologies are available. The instruments are designed to meet a variety of needs.
- Testing can be conducted in-house, with the pretrial services program responsible for conducting the tests, or by contract with an outside laboratory. The advantages and disadvantages of both approaches should be weighed by each program in light of its situation and needs.

Notes

1. References are made in this section to various manufacturers or vendors of testing technologies and systems. Such references are made to provide readers with complete information on the options available to test urine specimens for drugs of abuse. References are not intended and should not be construed as endorsements of any product or manufacturer.

2. Produced by the SYVA Company, P.O. Box 10058, Palo Alto, CA 94304, 1–800–227–8994.

3. Produced by Abbott Labs, P.O. Box 15202, Irving, TX 75015, 1–800–527–2547.

4. Produced by Roche Diagnostics, One Sunset, Montclair, NJ 07042, 1–800–526–1247.

5. National Institute of Justice and Bureau of Justice Assistance, *A Comparison of Urinalysis Technologies for Drug Testing in Criminal Justice*, Washington, D.C., 1991, p. 27.

6. The above-noted NIJ/BJA study contains a more detailed discussion on the use and limitations of immunoassay and chromatography methods.

7. *Lahey* v. *Kelly*, N.Y. 2d 135 (N.Y. Ct. App., 1987); *In re Johnston* (Wash. Sup. Ct., No. 53580–9, 1987); *Spence* v. *Farrier* (CA8, No. 85–902, 1986); *Harmon* v. *Auger*, 768 F. 2d 270 (8th Cir., 1985); *Jensen* v. *Lick*, 589 F. Supp. 35 (D.N.D., 1984); *Vasquez* v. *Coughlin*, 499 N.Y.S. 2d 461 (Sup. Ct. App. Div., 1986); and *Peranzo* v. *Coughlin*, 608 F. Supp. 1504 (S.D.N.Y., 1985). One court has ruled that an unconfirmed positive result was admissible as evidence in a contempt of court proceeding (*U.S.* v. *Roy*, Crim. No. 12098–84, D.C. Super. Ct., 1986). Another found unconfirmed results to be "presumptively reliable and thus generally admissible into evidence in every case" (*Jones* v. *U.S.*, No. 86–31, D.C. Ct. App., 1988).

8. The cutoff can be set low to be very sensitive (thus minimizing the chance of false negative results); however, the lower the cutoff, the greater the chance of obtaining false positive results. Setting the cutoff at a high level will increase the chance of obtaining false negative results. The manufacturers of the immunoassay technologies listed above preset the cutoff of the test to a level that places greater emphasis on minimizing the chances of obtaining false positive results. In 1988, the National Institute on Drug Abuse published the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (see *Federal Register*, vol. 53, no. 69, April 11, 1988). These guidelines specify the policies and procedures to be used by any laboratory to test urine specimens of Federal employees. Included in the guidelines are the cutoff levels that must be used when testing specimens obtained from Federal employees. Even though these guidelines do not apply to testing of criminal justice system clients, the specified cutoff levels are the same, with minor exceptions, as the cutoff levels that are preset by the manufacturers of the immunoassays.

9. However, the contract laboratory may arrange to set up an onsite testing facility, testing the specimens in the same proximity to the jail or courthouse as with an in-house testing facility. In Maricopa County, for example, the contracted laboratory (TASC) set up testing equipment in the county jail.

10. The NIJ/BJA study of testing technologies found that, when using established cutoff levels, "no one type of immunoassay was consistently superior to the others in identifying positive and negative specimens" (National Institute of Justice and Bureau of Justice Assistance, *A Comparison of Urinalysis Technologies for Drug Testing in Criminal Justice*, Washington, D.C., 1991, p. 27).

11. According to the 1988 "Mandatory Guidelines for Federal Workplace Drug Testing Programs," a laboratory is authorized to test such specimens only if it has been certified by the National Institute on Drug Abuse as having met all provisions of the guidelines. These guidelines do not apply to testing of criminal justice system clients.

12. TASC programs make community-based treatment available to drug-dependent offenders. They combine the influence of legal sanctions with innovative criminal justice system dispositions such as deferred prosecution, community sentencing, diversion, pretrial intervention, probation, and parole supervision to motivate substance abusers to cooperate with treatment. TASC programs receive funding from the Bureau of Justice Assistance and operate in many sites across the country.

13. Michael E. Peat, "Analytical and Technical Aspects of Testing for Drug Abuse: Confirmatory Procedures," *Clinical Chemistry*, vol. 34, 1988, p. 472.

14. *Estimating the Costs of Drug Testing for a Pretrial Services Program*, Washington, D.C.: Bureau of Justice Assistance, 1989.

CHAPTER VI. CONFIDENTIALITY

Maintaining confidentiality means limiting access to test results and other program information on the defendant, such as scheduled testing appointments and compliance to the drug testing condition. Confidentiality further means limiting the use of such information. Thus confidentiality procedures ensure that test results are released:

- Only to agencies and persons with accepted access to them and used by those agencies for accepted purposes.
- Only as a means of setting conditions of pretrial release and penalties for violating pretrial conditions.
- Only in writing or in person.
- Following applicable Federal, State, and local confidentiality laws.

The policies outlined in this chapter are common to the demonstration programs and should conform to all Federal and most State and local standards. However, program administrators should still consult their State and local confidentiality policies before drafting their own guidelines.

Federal Confidentiality Guidelines

All federally assisted programs must conform to Federal rule 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule.[1] Federally assisted programs include:

- Programs conducted directly by a Federal agency or through a contract with the agency.
- Programs operating under the authority or through license of a Federal agency. These include providers of Medicare services and agencies licensed to dispense methadone and other controlled substances.
- Programs supported by Federal funds. These include recipients of Federal financial assistance, programs conducted by States or localities receiving Federal funds that could be (but are not necessarily) spent on drug or alcohol abuse programs, and programs given tax-exempt status or to which taxpayers can make tax-deductible contributions through the Internal Revenue Service.

Additionally, any agencies referring defendants to drug testing or treatment programs fall under 42 CFR.

Rule 42 CFR covers any information obtained by federally assisted programs that may directly or indirectly identify a person as a drug user. In a health care setting, all program information regarding patients is confidential. Under limited circumstances, and usually with the patient's consent, health care or treatment programs can release information to other parties. These parties receive information only as needed to carry out a specific duty involving the patient.

In a criminal justice setting, Rule 42 CFR forbids agencies receiving drug test information from using that information as evidence in a pending charge against a defendant who is in a drug testing or treatment program.[2] However, courts ordering defendants into drug testing or treatment can receive information to monitor the defendant's compliance with conditional release.[3] Other criminal justice agencies can receive drug test information to perform specific duties regarding the defendant. Generally:

- Courts should receive information to set conditions of pretrial release and condition violation hearings. A program may also inform the court of a defendant's compliance (positive tests and record of appearance) before each court date.
- Defense counsel should have full access to a defendant's drug test results to help prepare arguments for bond hearings and help gauge a defendant's possible drug treatment needs. A

program should verify that the attorney is the counsel of record before releasing information.

- Prosecutors should receive drug test information to prepare arguments for bond hearings and to request modifications or revocation of pretrial release.

State and Local Confidentiality Guidelines

States may have separate confidentiality guidelines for drug test information. Rule 42 CFR allows States to prohibit certain disclosures that Federal guidelines allow, so some State guidelines may have tighter restrictions on releasing information. However, States cannot permit disclosures forbidden by 42 CFR.[4]

Some pretrial programs have statutes or agreements with the local court restricting the use of program information. Since pretrial drug test results are agency information, they fall under these local guidelines. For example, under the Washington, D.C., bail statute, pretrial agency information can be used only to set bond; in hearings to determine sanctions for noncompliance with release conditions, failure to appear, and rearrest; and in perjury and impeachment-of-testimony proceedings. Agency information cannot be used to determine guilt.[5] In Arizona, a committee formed by the State Supreme Court has proposed to the legislature that pretrial drug test results be used only to set conditions of release, determine compliance to court orders, and assess defendants' treatment needs.[6]

Pretrial programs without local guidelines about using program information should include restrictions on use of drug test results in their Memorandum of Understanding (see Chapter I, Gaining Support From Criminal Justice System Representatives, for a complete discussion of the Memorandum of Understanding).

Release of Information

Only certain individuals or agencies are authorized to receive drug test information. Pretrial drug testing programs should release information without a defendant's signed consent only to agencies participating in the Memorandum of Understanding. Usually, these include the courts, prosecutors, supervision agencies, defense attorneys, and probation and parole departments. Pretrial programs should not release program information to victims, the media, or police.[7] Laboratories contracted to test urine specimens and treatment facilities used by the pretrial program should release information only to the pretrial program.

To ensure this restricted access, programs should develop written policies on releasing information. The procedures should cover how to release information and how to record releases; they should be included in the program's procedures manual.

Information on drug test results should be released in person or by phone only after persons requesting it satisfactorily identify themselves and explain why they want the information. Persons should receive information only to carry out duties specified in the Memorandum of Understanding, and only specific employees should be authorized to release information and record release transactions.

Second Party Release of Confidential Information

Rule 42 CFR stipulates:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is not sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any drug or alcohol abuse patient. A person who receives confidential information, pursuant to his/her responsibilities in a criminal justice agency, concerning a client whose participation in a program was made a condition of the disposition of charges, release from custody, or probation, may redisclose and use it only to carry out official duties with regard to the client's conditional release or other action in connection with which the consent was given.

All releases of information should be recorded. The record should include the name of the employee releasing the information, the recipient of the information and his or her reason for requesting the information, and the date and time of receipt. Recipients of test information should receive a written statement informing them that in accordance with 42 CFR they are prohibited from giving released information to another party.

Defendant Consent to Information Disclosure

Generally, 42 CFR forbids disclosure of program information without a defendant's consent (this does not include information given to criminal justice agencies for performing a specific duty related to the defendant). Rule 42 CFR requires programs to use written consent forms when obtaining a defendant's consent. These forms must have the defendant's name, the name of the drug testing program, the name of the requesting party, and the purpose of the disclosure. The forms must also have space for the date of the disclosure and the defendant's signature or the signature of a person authorized to sign for the defendant. The forms should also provide a line for a program employee to sign as witness to the defendant's or designate's signature.

When parties other than those who signed the Memorandum of Understanding request information, programs should investigate whether release would be appropriate. Release to persons not bound by the Memorandum of Understanding should be related to pretrial supervision in the pending case (third-party supervision or placement into a drug treatment program, for example). Rule 42 includes the following sample consent form, which complies with its guidelines.

Record Security

To ensure the confidentiality of drug test information in their possession, programs should secure all written records in locked areas, with access limited to persons authorized to release information. Computer terminals in automated recordkeeping systems should be locked, and access to certain information should be available by password only. Programs should also have written procedures regulating who has access to written records and for what specific purposes.

Performance Measures

Any breach in confidentiality procedures should be reported to the appropriate program officials and investigated. Program officials should also periodically review practices for release of information to make certain that staff are following procedures.

Exhibit 6–2

Sample Consent Form

Sample Consent Form

I (name of patient/defendant) _____ request _____ authorize (name or general designation of program which is to make the disclosure) to disclose (kind and amount of information to be disclosed) to (name or title of the person or organization to which disclosure is to be made) for (purpose of the disclosure).

_____

Date

_____

Signature of patient/defendant

_____

Signature of person authorized to sign in lieu of the patient/defendant (where required)

_____

Witness

This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon (specific date, event, or condition).

Summary of Major Points

- Federally assisted drug testing programs must conform to the confidentiality guidelines outlined in 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records, Final Rule, which generally regards all program information about defendants as confidential. Programs receiving test information must also follow Federal 42 CFR.
- Under limited circumstances, programs can release information to other parties, but only as needed to carry out a specific duty involving the defendant.
- Release of information to anyone other than parties to the Memorandum of Understanding requires the defendant's written consent and a legitimate reason for requesting the information.
- Programs should have written procedures for releasing information.

Notes

1. *Federal Register*, vol. 52, no. 110, June 1987.

2. 42 CFR Part 2, Sec. 2.12(d).

3. 42 CFR Part 2, Sec. 2.35(a).

4. 42 CFR Part 2, Sec. 2.20.

5. District of Columbia Code, 1981 Edition, Vol. 5, Sec. 1303(d).

6. Arizona Supreme Court Committee on Drug Testing, *Arizona's Pre-Adjudication Drug Detection Program*, Arizona Supreme Court Administrative Office of the Courts, January 1988, p. 35.

7. While supplying test results to persons outside the criminal justice system is discouraged, programs may wish to give results to a defendant's family members or employers, with the defendant's signed consent. Pretrial programs may want to consult with their jurisdiction's attorney on whether such disclosure is acceptable.

PART THREE: MANAGEMENT ISSUES

CHAPTER VII. STAFFING

A drug testing program requires an adequately sized and trained staff to perform its functions. There should be enough staff to observe chain of custody requirements during collection and transport of urine specimens to the laboratory. The staff should be able to test specimens, process program information, and supervise defendants ordered into pretrial drug monitoring. Several factors determine a drug testing program's staffing needs.

The first is the size of the target population and the rate of supervised release. If the program does pre-initial-appearance testing, the target population will determine how many specimens are collected and tested. The expected rate of supervised release after introducing drug testing will determine how many defendants will be placed into pretrial drug monitoring.

The number of hours of operation also affects staff size. Drug testing programs will need staff to cover all urine collection and testing shifts. A program collecting and testing specimens only during standard business hours (for example, 8 a.m. to 5 p.m.) will require less staff than one operating around the clock.

The size of the staff also depends on how much of the program is conducted by the agency and how the responsibilities are allocated. Programs collecting and testing specimens in-house will require more staff than programs contracting these jobs to a laboratory. Programs incorporating collection or supervision duties into the work of the pretrial interview staff will also require less staff for their drug program.

An agency's financial resources inevitably affect the nature and scope of the drug testing program. Some jurisdictions will have the budgetary means to staff an in-house laboratory with collection, supervision, and laboratory staff. Others may need to incorporate these duties into those of the present pretrial staff or contract them out to a laboratory. When figuring staff costs in a budget, program administrators must remember that sufficient staff are needed to ensure the privacy and due process rights of defendants tested and to help prevent legal challenges to the drug testing program. Programs unable to hire adequate numbers of new staff or pass along drug testing functions to current staff should reduce the defendant population that is targeted for testing.[1]

Staff Positions and Duties

Five positions are common to pretrial drug testing programs. Which positions a program fills depends on what jobs are done in-house and what jobs are done by existing pretrial program staff.

Program supervisor. The program supervisor oversees the daily operation of the drug testing program and ensures adherence to written protocol. The supervisor also hires and trains new staff, schedules and staffs testing and collection shifts, and updates the procedures manual. The program supervisor should be well acquainted with the program's testing technology and testing instrument and be able to explain the testing procedure to the court and program staff. The Washington, D.C., program uses two supervisors in its drug testing components. One supervisor manages the collection, data entry, and supervision staff, and the other supervises laboratory operations. The Milwaukee County demonstration program has also used this arrangement.

Supervision officers. These officers monitor defendants in the program, reassigning them from one level of supervision to another, and refer defendants to treatment. Supervision officers also draft violation and status reports for the court and represent the program at court hearings.

How a pretrial program staffs its supervision component is important since drug testing most likely will increase the number of defendants supervised. To help manage the increased numbers, pretrial programs may incorporate drug testing supervision officers or supervision of the drug testing condition into

the regular pretrial supervision office. This was done by the programs in Pima, Multnomah, Milwaukee, and Prince George's counties. The Los Angeles County and D.C. programs created new units to monitor the drug condition.

Specimen collectors. These staff persons identify defendants for drug testing, explain the purpose and use of pre-initial-appearance tests to defendants, and directly observe defendants submitting specimens for both pre-initial-appearance testing and pretrial drug monitoring. Specimen collectors also carry specimens to the testing facility, observing proper chain of custody requirements. Often, contracted laboratories collect urine specimens.

Testing technicians. Testing technicians, or laboratory staff, test urine specimens, calibrate and maintain the testing machinery, and maintain inventory of laboratory supplies. They also monitor the accuracy of test results and must be proficient in the testing technology the program uses.

Data entry staff. Programs may employ staff to enter data into the information system or assign data processing to other staff, such as supervision officers. Programs with multiuser or mainframe automated information systems (see Chapter VIII, Information System) should hire a system administrator to maintain the system and oversee data entry.

Recruiting and Hiring Staff for an In-House Testing Program

Laboratory staff of drug testing programs usually come from the departments of chemistry, medical technology, or forensic science of local schools. While programs may prefer staff with these backgrounds, the technologies generally used for urine testing in criminal justice do not require prior experience in these fields. Most of the demonstration programs hired collection, data entry, and supervision staff from the same hiring sources as they did interview and other supervision staff.

Local hiring policies usually determine how quickly the program can staff and begin a drug testing program. Usually, programs fit under one of the following hiring policies.

The pretrial program hires staff independently. Some pretrial systems can independently post job announcements, screen candidates, and select new staff. Usually, these programs will bring on prospective employees quickly.

The pretrial program posts jobs through its parent department. Pretrial programs under a court, probation, corrections, or other department post job announcements through the department's personnel office. Either the personnel office or the pretrial program interviews and selects applicants.

The jurisdiction hires for all public jobs. Some jurisdictions have a central personnel office for public sector jobs. This office interviews applicants and sometimes gives a civil service exam. Applicants who pass this exam are placed on an employee list. Agencies needing employees pick applicants from this list.

When planning a pretrial drug testing program's timetable, program administrators should consider which hiring policies are in effect in the jurisdiction and allot enough time to follow them.

Staff from other pretrial program departments can assume some duties of drug testing. For instance, interviewers can collect specimens, and supervision officers can monitor the drug testing condition. However, staff should not be forced into doing these functions or they may not do them well or at all. Interviewers may decide not to collect specimens from all eligible defendants, and supervision officers may give the drug testing condition lower priority in their caseloads. Moreover, drug testing program functions may disrupt the staff's current duties. In Pima County, interviewers volunteered to collect urine specimens to help increase the rate of specimen collection. However, interviewers were unable to collect specimens and still finish interviews in time for court. This prompted program officials to staff a separate unit of urine specimen collectors.

Before using existing staff to perform drug testing functions, program administrators should gain staff support for drug testing and for assuming some drug testing duties. If support cannot be found or generated, existing staff should not be used. Even if support for drug testing is high among staff, administrators must decide if adding drug testing functions to staff responsibilities would overburden employees.

Training, Certification, Compensation, and Turnover

Training of staff is important and can take several forms and proceed at several levels. Program administrators should set up a training program to acquaint supervisors with program policies and procedures. Supervisors in turn should train collectors and data entry staff. For the demonstration programs, training sessions usually took 2 to 3 weeks.

In addition, the testing instrument manufacturer should train and certify testing technicians on the laboratory machinery. Manufacturers run special training programs that last from 2 days to 1 week. Employees should also be kept up to date with advances in testing technology. Some manufacturers also send out newsletters to laboratories that help them do this.

The testing program must verify that the contracted laboratory's specimen collectors and testing technicians meet the job requirements noted above and are certified by the testing instrument manufacturer. The program must also verify if laboratory staff meet applicable State requirements for operating testing instruments.

Salaries for drug testing staff should be the same as those for comparable pretrial or probation program staff, and the pay scale of the testing program's supervisor should follow that of other department supervisors. Collectors' salaries should likewise follow those of interviewers, and supervision personnel income should be comparable to that of other supervision officers.

Each demonstration program had periods of high turnover. Collectors tire of gathering urine specimens daily. Laboratory staff who become proficient in laboratory procedures may not feel challenged by daily testing and choose to leave. Program administrators should anticipate regular turnover in the drug testing program and keep a network of hiring sources for future employees.

Performance Measures

The drug testing program will not operate efficiently if the size of the staff is not sufficient to meet the demands of the program or if staff have not been sufficiently trained. Officials should review the functions performed, the hours of operation, the amount of work completed, and the quality of the work to determine if the size of the staff is appropriate and if any additional training is required.

Summary of Major Points

- Staff size depends on the number of employees the testing program needs to operate efficiently. There should be enough staff to collect specimens properly and observe chain of custody requirements, test specimens, process program information, and supervise defendants ordered into supervised testing.
- The jobs common to a pretrial drug testing program are a program supervisor, specimen collectors, drug testing technicians, supervision officers, and data entry staff. Programs with automated information systems may wish to hire a system administrator to maintain the information system.
- Staff from other pretrial system departments can take on some duties of drug testing. The existing staff should be part of and approve any decision to add new duties to their existing jobs. Program administrators could also add drug testing functions to the job descriptions of new pretrial services officers.
- All staff must be trained to perform their jobs. Supervisors should train collectors and data entry staff. Testing technicians should be trained and certified by the testing instrument manufacturer. Afterward, employees should be kept up to date with advances in testing technology.

Notes

1. For a more detailed discussion of budget costs, see *Estimating the Costs of Drug Testing for a Pretrial Services Program*, Bureau of Justice Assistance, June 1989.

CHAPTER VIII. INFORMATION SYSTEM

Drug testing requires an information system for recording program information, reporting information to other parties, monitoring defendants in drug testing, and protecting the confidentiality of test results. This information system should provide program administrators with the means to organize, research, and control the operations of the drug testing program. Many pretrial programs have information systems that handle pretrial interview, criminal history, and other program information. For these programs, processing drug test information means adapting the current system to record drug tests and monitor defendants ordered into testing.

Capabilities of an Information System

An information system should allow a pretrial drug testing program to perform the following functions:

Process all program information. The information system should allow program staff to enter and retrieve drug test results, testing schedules, compliance reports, and violation notices. The system should catalog information by a defendant's name, identifying number, and case number.

Monitor the performance of defendants placed into pretrial drug monitoring. Programs should know the status of each defendant in pretrial drug monitoring. Monitoring information includes all test results; the defendant's current testing schedule, sanction level, and next appointment date; the results of any court hearings; and referrals to treatment.

Draft violation notices, status reports, and operational reports. The system should allow program staff to access information that will enable them to draft reports to the court and other parties. Automated information systems should allow the program to print operational reports such as daily schedules of drug test appointments and lists of defendants in violation of the drug testing condition.

Manage the flow of information between the drug testing program and other parties. The system should permit program staff to transmit information to and receive information from other agencies, particularly test information from contracted laboratories. If the system is on a mainframe computer, it should restrict the access of other parties on the mainframe to test information.

Evaluate the drug testing program and the drug testing condition. The information system should allow the program to evaluate the effectiveness of the drug testing condition and of program practices, as recommended by the National Association of Pretrial Agencies.[1] To evaluate drug testing, the information system must process demographic information on tested defendants, the rate of positive tests, charge information, and case outcome. To evaluate the drug testing program, the information system should process the rate of specimen collection, the efficiency of reporting test results, and the results of proficiency testing.

Determine the rate of drug use and the types of drugs used. The information system should allow local officials to regularly track the drug use trends in the arrest population.

Types of Information Systems

Information systems are either manual or automated, but programs with automated systems usually keep hardcopies of all the information entered in the automated system.

Manual systems. Manual systems file copies of program information under a defendant's name, identifying number, or case number. Information such as prior arrests may be stored in books or in files, with card indexes cataloging the books or files containing certain information. Each card holds the defendant's name, date of birth, and identifying number and the

book, file, and page containing other defendant information.

Automated systems. These systems use computers to store information, either microcomputers, minicomputers, or mainframes.

Microcomputers, or personal computers (PC's), are the smallest and, usually, least expensive computers. They can be fitted with floppy or hard disk drives and can run various software packages. Most microcomputers are compatible with IBM microcomputers—the PC, XT, AT, or PS/2. They can be used as single-user systems or combined into a multiuser system, or local area network (LAN). A file server—a computer with large storage capacity and fitted with the LAN's operating software—links the PC's together and acts as the system's main storage unit. PC's on a LAN share information and applications such as additional storage and printers.

Minicomputers are multiuser systems often employing one central processing unit and several dumb terminals—visual display terminals with no processing ability. Examples of minicomputers include the IBM AS400 and System 36/38, and Digital Equipment Corporation's Microvax.

Mainframes are larger than LAN's and minicomputers and can hold more information. They can contain several individual automated systems. Each individual system may have access to some or all information stored under other systems in the mainframe.

On an automated system, screens emulate the hardcopy forms used with manual systems. Each screen is prompted by the defendant's name, identification number, or case number. Most automated systems also have manual backups of information in case the automated system is inoperable.

Choosing an Information System

Both manual and automated systems have strengths and weaknesses. Generally, manual systems are less expensive and easier to set up and maintain. They may be ideal for drug testing programs with low volumes of information and minimal information processing needs. However, manual systems may limit a program's ability to research the efficiency of the drug testing program and the drug testing condition. Programs using manual systems may also be unable to generate certain operational reports quickly or at all.

Automated systems cost more than manual systems and require more effort to maintain. In a mainframe shared by different users, drug testing staff may often wait behind other system users to enter and retrieve information. Automated systems may also have significant downtime when the system is not accessible. However, an automated system can handle larger volumes of information and provide the program with better research and report-generating capabilities.

Several factors affect the choice of a manual or automated information system, as described below.

Anticipated volume of testing. To anticipate the volume of information after integrating drug testing, a pretrial program must estimate whether drug testing will increase the number of defendants released into its custody with the drug testing condition. Programs anticipating a small increase may opt for a manual information system or a single microcomputer fitted with data base software. Jurisdictions expecting a larger increase in volume may need an automated system. The Pima, Multnomah, and Prince George's County programs switched from very good manual systems to computers because of an increase in conditionally released defendants.

The capability of the current information system. The present information system may be enough to handle the information needs of a drug testing program or may need only a simple upgrade. The Washington, D.C., pretrial program, which is part of a mainframe, enhanced its own information system to incorporate drug test information. Officials in Milwaukee updated their LAN system to include drug test information.

Anticipated use of the information system. Programs planning only to track a defendant's progress through the drug testing program may need only a manual system. Programs planning to research drug testing as a release condition or monitor the efficiency of the pretrial drug testing program may prefer an automated system. Programs wishing to streamline information entry or upgrade the capacity to generate operational reports may also need an automated system.

Processing Drug Testing Program Information

Test results. The information system should catalog results from all drug tests, including the test date and results, the collector's name or initials, the type of test, and the next scheduled test date. Also included should be the defendant's present status in the program, such as current testing schedule and sanction level. Exhibit 8–1 is a variation of the test result screen used by the D.C. program in its automated system. Though formatted for a computer, the screen can be adapted to a manual system.

Some testing instruments can be programmed to file test results directly into an automated system. Programs using these instruments also make hardcopies of test results and file them with other information on compliance to pretrial release conditions. Program administrators should determine through the manufacturer the testing instrument's ability to interface with existing computer systems.

Programs contracting testing to an outside laboratory must include in their information system the method for transferring test information from the laboratory to the program. For example, programs can use facsimile machines or modems to transmit test results. On automated systems, the information could go directly into the data base. On manual systems, a hardcopy of the information goes to the program. Program staff record each test result in the defendant's file and keep the hardcopy as a log of the

Exhibit 8–1

Sample of a Test Result Screen

Substance Abuse Detail

(Date of data entry)

(Identifying number) Name:_____

Defendant's testing schedule: _____

Defendant's current status in program: _____

Defendant reports using: _____ Within: _____ (W=Week, M=Month)

Test date: _____ Test: _____
(S=Scheduled, U=Unscheduled, L=Lockup, O=Other)

Escorted by: (Collector's initials)

Test results:

Amphetamine: _____ (P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)

Cocaine: _____ (P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)

Methadone: _____ (P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)

Opiates: _____ (P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)

PCP: _____ (P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)

Next test date: _____

day's test results. Another option is hand-delivering results from the laboratory to the testing program.

Initial release records. These should include the drug testing condition, since the drug conditions become part of the court's release order. Programs should keep hardcopies of the release forms used by the court and the form outlining the conditions of pretrial release, including the drug condition.

At the initial test, program staff should log the defendant's results and appointment schedule into the information system. Using the substance abuse detail screen described in exhibit 8–1, an initial test would appear as shown below.

Tracking Defendants Placed Into Pretrial Drug Monitoring

The information system should permit entry and retrieval of information on scheduled dates and on defendants' current program status. It should also generate reports to reduce the work needed to supervise drug program defendants.

Programs should record all test results on the drug test recording form or the formatted computer screen or both. The information system should group the test results under the defendant's name and identifying number or under the case number. Each test result should have the defendant's test schedule, next test date, and status in the program.

Exhibit 8–2

Completed Sample Screen

Substance Abuse Detail

01–01–92

1234567 ***John Doe***

Defendant's testing schedule: _____

Defendant's current status in program:_____

Defendant reports using: ***Cocaine*** Within: ***W*** (W=Week, M=Month)

Test date: ***01–01–92*** Test: ***L***
(S=Scheduled, U=Unscheduled, L=Lockup, O=Other)

Escorted by: ***DC*** (Collector's initials)

Test results for:

Amphetamine:	***N***	(P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)
Cocaine:	***P***	(P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)
Methadone:	***N***	(P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)
Opiates:	***N***	(P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)
PCP:	***P***	(P=Positive, N=Negative, 0=No test, D=Did not submit, F=No show, J=Jail)

Next test date: ***01–08–92***

Exhibit 8–3

Sample Drug Testing Log

Daily Drug Testing Log: (Date)

Doe, John DOB: _____ Identifying number: _____ Testing schedule: _____

Case number: _____ Next court date: _____ Judge: _____

Defendant's address: _____ Phone: _____

Last test date: ____ Results: (Drug: Positive/negative, failed to report, unable to submit, excused)

Test date: ____ Results: (Drug: Positive/negative, failed to report, unable to submit, excused)

Test date: ____ Results: (Drug: Positive/negative, failed to report, unable to submit, excused)

Current status: (In compliance, in technical violation, violation notice sent, terminated)

Next scheduled drug test: _____

Collector: _____ Time of collection: _____

Time sample taken to laboratory: _____

Review release conditions: _____ Check address: _____

Review court date: _____ Review next test date: _____ Reviewer: _____

For each test date, the information system should generate a list of defendants due for testing. In addition to the name and identifying number of each scheduled defendant, this list may contain the results of the previous drug test (positive for what drug, failure to report, excused absence) and the defendant's sanction level.

Drafting Violation Notices, Status Reports, and Operational Reports

A manual information system should allow the program to create violation and status reports to the court, prosecutors, and defense attorneys. This requires quick access to a defendant's current status, record of test dates, results and appearances, case number, and next court date. An automated system should allow the program to generate these reports automatically.

A manual information system should keep all information on a single pending case together in one file. Each case file should go into a larger file of defendant information. This allows program staff to check compliance in several pending cases at once. One type of compliance file is a log of condition compliance. The log should include the release date and conditions, test dates and results, internal and formal sanctions, and running commentary on compliance.

An automated system should have a supervision subsection logging release conditions and compliance. This subsystem should be similar to the manual compliance log and should include the full record of defendant reports including testing appointments, internal and formal sanctions applied, and dates of court actions. Each supervision log should pertain to a single pending case.

Status reports. Programs may opt to send status reports to judges on the dates a defendant is due in court. Usually, these reports are compilations of the defendant's scheduled testing appointments to date. Each test date includes the result of each test.

Exhibit 8–4

Sample Violation Report

Violation Report

(Date)

To: (Judge's name)
From: (Program staff person)
Re: Defendant: _____ DOB: _____
Case number(s):_____

Your Honor:

On (date), the above-named defendant was released to the supervision of this agency with the following conditions:

(Release conditions)

The following violations are alleged: _____

The defendant has failed to report for scheduled drug testing on: _____

_____

The defendant tested positive for drug use on the following dates: _____

_____

Other violations:_____

_____

Recommendation:

_____ Release with the following conditions:_____

_____

_____ Revocation of release and a contempt sentence of _____, followed by release on the following conditions: _____

Violation reports. Violation reports account for the specific violation reported, attempts to bring the defendant in compliance, and recommended sanction (see exhibit 8–4). Besides making this information readily available, the information system is likely to make drafting the report easier. Most automated systems can combine information from different subsections onto a report. Stand-alone PC systems should include templates of the standard violation form. The template is similar to a hardcopy form, and program staff fill in information at various prompts on the screen. If the program has a variety of recommended sanctions, the screen should include information on when each sanction should be recommended.

Evaluating the Drug Testing Program and the Drug Testing Condition

The information system should allow program administrators to assess the effectiveness of drug testing and the operation of the drug testing program. It should allow for collecting trend data such as rates of positive results and specimen collection, and the types of defendants testing positive. It should also allow program staff to analyze the data in these categories. Automated systems should have the capacity to generate statistics from the data collected.

Exhibit 8–5

Checklist for Assessing Information Processing Needs

Need	System Capability
Processing program information.	Easy entry and access; cataloging of drug test information by the defendant's name, identifying number, or case number. Manual forms, computer screens, or both to enter information.
Monitor defendants placed in the testing program.	Screens or forms to record drug test results, appointments, current status in the testing program, violations forwarded, and treatment referrals made.
Protect the confidentiality of test results.	Automated information systems that can restrict information to unauthorized users. Manual records locked and restricted by a staff person.
Create notices and reports.	Automated systems with report-generating ability. Manual reports requiring specific information on the defendant and the violation. Automated templates with formatted reports.
Evaluate the drug testing program and the testing condition.	Codifying of data in demographic categories such as age, race, sex, rate of positive tests, rate of specimen collection, and defendants testing positive and negative. Running of statistical functions, or compatibility with statistical software.

Issues in Information Processing

Ensuring information flow and integrity. To ensure timeliness and consistency of information, programs should assign data entry duties to specific staff. These duties include entering test results, schedules, current status, and next test dates. If a program uses an automated system, staff should be assigned to generate and update operational reports. Staff should record information in the automated system and make a manual copy as a backup.

Programs with automated information systems should also hire a qualified system administrator to trouble-shoot problems that occur and to work to enhance the system. Pretrial drug testing programs with either automated or manual information systems might consider staffing a data processing unit to check the accuracy of the information entered and to back up system information.

Automated systems can crash. The system may malfunction due to a hardware malfunction or problems in the software. To protect records from equipment failure, the program should keep hardcopy information records as backups. The data processing staff or system administrator should create and maintain the backup records.

Ensuring confidentiality. If drug test information is kept on a mainframe shared by other users, the pretrial program must restrict access to the information. One way of doing this is by coding test result screens so that only terminals operating in the pretrial program can see them. Computer units can be fitted with passwords to certain screens and locked after business hours. Either the supervisor or system administrator should lock up manual records and determine access to them.

Exhibit 8–5 shows how programs can select information system capabilities that meet their specific needs.

Performance Measures

In reviewing the performance of the information system, program administrators should evaluate how quickly staff can access data and generate notices and reports. They should also assess the security of test results within the system. Any instances in which an unauthorized party gained access to the system must be investigated and any problems rectified immediately. Officials should also examine whether the system is capable of efficient data entry and retrieval of drug test information. A pattern of inability to access information because of computer failure or other problems must be addressed.

Summary of Major Points

- An information system should allow the pretrial drug testing program staff to enter test results on pre-initial-appearance testing and pretrial drug monitoring specimens, monitor the performance of defendants in pretrial drug monitoring, draft violation notices and status reports, and evaluate the drug testing program and the drug testing condition.
- An information system may be manual, automated, or a combination of both. Automated systems include microcomputers, minicomputers, local area networks, or mainframes.
- Whether a program uses an automated or a manual system depends on the volume of testing it anticipates, the capacity of its current information system, and anticipated use of the information system.
- If a program uses an automated system, it should keep hardcopies of information such as test results, referral notices, and violation requests. Staff should store these forms in a file containing information on compliance with all release conditions.
- An information system should keep all information on a single pending case together in one file. Manual systems could incorporate a log of condition compliance. The log should include the release date and conditions, test dates and results, internal and formal sanctions, and running commentary on compliance. Automated systems should have a supervision subsection logging release conditions and compliance and should include the full record of defendant reports including testing appointments, internal and formal sanctions applied, and dates of court actions.

Notes

1. National Association of Pretrial Services Agencies, *Performance Standards and Goals for Pretrial Release and Diversion: Release, Standard XIII*, July 1978, p. 71.

CHAPTER IX. PROCEDURES MANUAL

The procedures manual is a guidebook of the testing program's policies and procedures and is a necessity for a pretrial drug testing program. It is a training tool for new employees and a reference for current employees and persons outside the drug testing program.[1] The procedures manual explains how the program targets defendants for testing, collects and tests urine specimens, supervises defendants ordered into pretrial drug monitoring, releases drug test information, and handles violations of the drug testing condition. It also states which program staff are responsible for what function.

Writing the Manual

Before the procedures manual is drafted, all the functions of the drug testing program should be outlined, including:

- Targeting defendants for testing.
- Collecting urine specimens and observing chain of custody for pre-initial-appearance and pretrial drug monitoring specimens.
- Testing specimens including retesting and confirmation, and sending test results to court.
- Placing defendants into pretrial drug monitoring and creating testing schedules.
- Tracking defendants through the drug testing program.
- Responding to program violations and terminations from the program.
- Adhering to confidentiality requirements.

Staff members responsible for each function should be indicated, as well as the materials needed to perform each function (forms, testing paraphernalia, for example) and the entries that need to be made into the program's information system.

The manual should be written in language that is easily understood by persons unfamiliar with the program, and technical terms should be explained when they first occur. Sentences should be kept short and sections brief.

The manual should be organized to follow a defendant's progress through the drug testing program. In the first section, the procedures for targeting defendants for testing should be described. The second section should address obtaining consent, collecting specimens, and maintaining chain of custody. Later sections should describe the information system, sanctions for program violations, and confidentiality policy. Each section should be dated to show when it goes into effect and should list the staff members responsible for the tasks mentioned. For example:

Procedures Manual
Page _____

III. Chain of Custody
Unit: Urine Collection Personnel

Effective date: ____-____-____

Sections of the Manual

Targeting defendants for testing. The initial section should identify the defendants targeted for pre-initial-appearance drug testing; for example, all defendants or all felony-charged defendants. If the program does not conduct pre-initial-appearance testing, this section should tell how staff identify defendants for testing. For example, the procedures manual for the Pima County program describes the program's drug use assessment scheme for recommending pretrial drug monitoring. The manual for the Multnomah County program explains that program's requirements for recommending testing, which includes self-admitted drug use within the current year, pending drug charges, and drug convictions within 5 years. If the

program uses an assessment scale to select defendants, the manual should say which staff members perform the assessment and how. For example, interviewers may use the assessment scheme to recommend pretrial drug monitoring after determining a defendant's release eligibility.

Urine collection and chain of custody. This section should follow the procedures listed in this monograph under Chapter IV, Chain of Custody, and Chapter X, Legal Considerations in Pretrial Drug Testing. The section should instruct collectors to explain to defendants that pre-initial-appearance testing is voluntary, to make sure defendants understand the concept of voluntary consent, and to note the drugs and legal medication the defendants admit using.

The chain of custody discussion should detail the procedures for collecting urine specimens, guarding against tampering during specimen submission, and transporting specimens to the laboratory. The section should advise staff to take particular care when observing the voiding of the specimen during pretrial drug monitoring since that is when defendants can contaminate specimens.

Testing procedures. Testing procedures should describe how to perform initial tests, retests, and confirmation tests. Since initial testing should follow the testing instrument manufacturer's guidelines, these guidelines should be included in the body of this section. Policies for retesting and confirming positive results or results used in violation hearings should also be discussed.

Testing procedures should also explain the manufacturer's guidelines for properly operating and maintaining the instrument. Other testing procedures to be discussed include when and how to dispose of urine specimens and how to handle positive results that might have been caused by legal medications (see Chapter V, Testing of Urine Specimens).

Testing schedules in pretrial drug monitoring. The manual should state how defendants ordered into pretrial drug monitoring will receive their next testing appointment and how the program determines a defendant's testing schedule (see Chapter III, Integrating Drug Testing Into the Supervised Release Process).

Violation procedures. The manual should list the sanctions for each instance of a positive test and missed appointment. It should state the exact response to an infraction, from an informal talk with the defendant about his or her compliance up to a formal request for bond revocation, and who carries out the response. The manual should tell the number of infractions after which violation notices are written; how the notices are prepared; and what recommendation, if any, is made to the court. A copy of the violation notice should be an appendix to the manual. The manual should also describe reduced requirements for defendants who abide by program conditions (see Chapter III, Integrating Drug Testing Into the Supervised Release Process).

Information system and case tracking. The manual should describe how the program tracks defendants through the drug testing program, including procedures for recording initial test results, placing defendants into pretrial drug monitoring, entering the results of scheduled drug tests, noting internal and formal sanctions used, and recording the information sent to the court and other parties (see Chapter VIII, Information System).

Confidentiality policies. The confidentiality policies listed in the manual should be the same as those in the Memorandum of Understanding. The manual should state who can receive program information and under what circumstances. It should also note when release of information to the Memorandum parties and other agencies requires a written consent form signed by the defendant. In addition, the manual should identify the staff responsible for releasing information and list the procedures for identifying parties requesting information, releasing the information, and logging the release in the program's information system. It should explain the procedures for storing program information.

The manual should also state to whom information is never released—such as the media and victims—and the policy on releasing information to the defendant's family, friends, or employer. Finally, the manual should explain the penalties for violation of confidentiality rules by program staff. This may include suspension or other disciplinary action, or job termination (see Chapter VI, Confidentiality).

Appendixes. The manual should include as appendixes any forms or memorandums mentioned in the text:

- The consent form used to explain the program to arrestees before pre-initial-appearance testing.
- The label placed on specimen bottles after a defendant submits a specimen.
- The urine collection log used to record specimen collection for pre-initial-appearance and pretrial drug monitoring.
- The assessment scheme or other criteria for recommending defendants into pretrial drug monitoring.
- The specimen transfer form used to record the urine specimens given to laboratory personnel.
- The form sent to court showing the results of drug testing.
- The exit interview form.
- The information system's log of scheduled appointments.
- The violation notice.
- Referral-to-treatment forms.

Other appendixes could include:

- Rule 42 CFR Part 2, the Federal standards for confidentiality of drug test results.
- The program's Memorandum of Understanding and other local directives relating to the program.
- Laboratory procedures for testing, if the program uses a contracted laboratory.
- The arrest charges making a defendant eligible for pre-initial-appearance testing or pretrial drug monitoring.
- The pretrial program's recommendation scheme.

Updating the Procedures Manual

The procedures manual should be updated whenever procedures change. Updates should be specific and should note the staff affected by the change and any new forms or computer entries required. The section should be dated to show the new procedure's effective date.

The procedures manual should be kept in a three-ring binder so staff can add or remove sections easily.

Summary of Major Points

- A procedures manual describes all the pretrial drug testing program's policies and procedures. It is a training guide for new employees and a reference for current employees and persons outside the program.
- The manual should note which person or unit is responsible for carrying out each function. It should be written to be easily understood by persons unfamiliar with the program. Sections should be brief, with technical terms explained, and should follow a defendant's progress through the program.
- Sections should include the dates the procedures went into effect. The manual should accommodate changes in program procedures and should be updated whenever procedures change. Updates should note the staff affected by the change and any new forms or computer entries.

Notes

1. In *Berry* v. *District of Columbia*, 833 F. 2d 1031 (D.C. Cir., 1987), the court quoted the D.C. pretrial drug testing program's procedures manual in its opinion. Both the U.S. Attorney for the District of Columbia and the local public defender quoted the manual in their *amicus curiae* briefs.

PART FOUR: LEGAL ISSUES

CHAPTER X. LEGAL CONSIDERATIONS IN PRETRIAL DRUG TESTING

Pretrial drug testing has experienced only one direct constitutional challenge,[1] but program administrators planning to integrate drug testing into their pretrial systems should note that every facet of drug testing is open to review. Since the constitutionality of pretrial drug testing is not a settled area of law, this monograph discusses only those relevant points addressed in current opinions, including:

- Fourth amendment requirements for the reasonableness of a search.
- Fifth and 14th amendment due process issues.
- Fourteenth amendment equal protection issues.
- Fourth amendment requirements for a consent search.

General Fourth Amendment Issues

The fourth amendment states that:

> The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.[2]

Traditionally, with noncriminal searches—those not conducted for evidence in a trial—courts determine reasonableness under the fourth amendment through a balancing test. This test requires courts to balance the need for the search against its intrusion into an individual's reasonable expectation of privacy. Considered in this balance is the reason for the search, whether individualized suspicion exists to search the individual or his belongings, and how the government conducts the search.[3] In 1989, the U.S. Supreme Court defined drug testing as a search under the fourth amendment.[4]

Pretrial drug monitoring. In 1987, the U.S. Court of Appeals for the District of Columbia ruled in *Berry* v. *District of Columbia*, 833 F. 2d 1031 (D.C. Cir., 1987) that pretrial drug monitoring was a search under the fourth amendment. Balancing governmental interests with individual rights, the court stated that a reliably proven, positive correlation between drug use and pretrial misconduct could overcome a defendant's privacy concerns.[5] The court also stated that testing procedures could be no more invasive than necessary and that once tested, an arrestee's placement into a drug testing program should be based on individualized suspicion of continued drug use.[6]

Pre-initial-appearance drug testing. The demonstration programs that perform pre-initial-appearance drug testing test arrestees in specific target populations without suspicion of individual drug use.[7] There may also be a question of whether at pre-initial-appearance the government has an interest strong enough to outweigh individual privacy rights.[8] To be reasonable, pre-initial-appearance drug testing may have to be exempt from the balancing test's requirement for individual suspicion and probable cause. One such exception, used by the current programs, is a search based on a defendant's voluntary consent. The requirements for a consent search and the procedures used by the demonstration programs to meet them are discussed later in this chapter.

Reasonableness of the testing method: determining the testing population, urine collection. How a drug testing program collects and tests urine specimens and who it tests will help determine whether the search is conducted reasonably. In public employee cases, courts have favored testing programs that create the most private and nondegrading testing atmosphere possible and that ensure against unnecessary disclosure of test results.[9]

Courts have also favored drug testing that is narrow in scope. The Supreme Court questioned whether the U.S. Customs Services should test employees in certain work categories[10] and the U.S. Court of Appeals

for the District of Columbia had doubts that all arrestees ordered into D.C.'s drug testing program were potential drug users.[11]

Due Process

The 5th and 14th amendments guarantee fair court proceedings before liberty is deprived[12] (procedural due process) and forbid government behavior that "shocks the conscience"[13] (substantive due process).[14]

Substantive due process: chain of custody, urine collection. In *Berry*, the defense argued that requiring arrestees to provide urine while being observed "shocks the sense of ordered liberty" and breaches substantive due process.[15] The appeals court did not address this point, but other courts have held that extracting body fluids, even forcibly, does not offend due process if done reasonably. In *Schmerber* v. *California*, 384 U.S. 757 (1966), for instance, the Supreme Court ruled that forcibly taking a blood sample conformed to due process because it was done in a hospital and blood extraction was a common and safe procedure.[16] Lower courts have ruled that drug testing complies with substantive due process when reasonable collection and testing procedures exist.[17]

Procedural due process: chain of custody, reporting violations of the drug testing condition. In public employee cases, courts have determined the presence or lack of procedural due process on the reliability of the testing method[18] and the need for a hearing before any adverse action (such as job termination or demotion).[19] To satisfy procedural due process requirements, testing programs must have in place a chain of custody policy for proper sample collection and handling, proper testing guidelines, and scientifically reliable testing technology[20] (see Chapter IV, Chain of Custody, and Chapter V, Testing of Urine Samples).

Reliability of testing technology: reporting violations of the drug testing condition. Most pretrial drug testing programs perform the initial test and retests using the immunoassay technology.[21] Courts hearing probation and parole revocation cases and considering impeachment of a defendant's testimony at trial have found that retests on immunoassay have reached a level of general acceptance in the scientific community and satisfy due process concerns.[22] Still, because immunoassays can produce false-positive results (specimens labeled positive when no drug is actually present), courts have recognized the importance of confirmatory testing (confirming against false-positive results), which can be done only by using more accurate technology.

The Test for Reasonableness

Berry v. *District of Columbia*, 833 F. 2d 1031 (D.C. Cir., 1987) is the only case to address the constitutionality of pretrial drug testing. In that case, the plaintiff—who was ordered into pretrial drug monitoring—challenged the D.C. pretrial drug testing program as violating his fourth amendment protection against unreasonable searches and seizures. The trial court ruled against him, finding that the drug testing program did not raise issues of "constitutional dimension" (*Berry* v. *District of Columbia*, No. 84-2659, slip op. at 7 [D.D.C. June 14, 1985]). However, the appeals court found that pretrial drug monitoring did amount to a search and seizure under the fourth amendment and reversed the trial court ruling. The appeals court also stated it could not rule on the drug testing program because the trial court's record "with respect to this issue is virtually barren" (*Berry*, 833 F. 2d 1031, 1034). It remanded the case for the trial court to make findings on the drug testing program's reasonableness, using the traditional balancing test. Among the issues for the trial court to consider are the possible correlation between drug use and pretrial misconduct, whether it was reasonable to assume that defendants ordered into the drug testing program are potential drug users, and the manner in which drug testing was conducted. The *Berry* case was eventually dismissed by the lower court in August 1991.

While the Berry court used the traditional balancing test to determine the reasonableness of pretrial drug testing, other courts may prefer to use the special needs test recently developed by the Supreme Court.

Equal Protection

The 14th amendment also prohibits differential treatment of similarly situated groups or persons unless there is a legally satisfactory reason. No court has yet determined that pretrial drug testing affects equal protection rights. However, the plaintiff in *Berry* argued that drug testing violated equal protection guarantees because arrestees released from police stations before the initial bond hearing, unlike those who remained in custody pending the bond hearing, were not tested.[23]

Consent

Whether consent to pre-initial-appearance drug testing is voluntary has not been formally questioned in any of the demonstration program jurisdictions. This could be due in part to the procedures used by the demonstration programs to ensure that consent to testing indeed is voluntary. Despite the lack of challenges, there are specific requirements for obtaining consent that programs must respect. Also, the Supreme Court has exempted searches based on consent from the fourth amendment's requirements for individualized suspicion.[24] Lower courts have ruled that valid consent negates the need to balance individual privacy interests to the government's need for the search since an arrestee waives those interests.[25]

The principal Supreme Court decision on consent searches is *Schneckloth* v. *Bustamonte*, 412 U.S. 218 (1973). In that case, the Court developed the "totality of the circumstances" approach to define coercion and the factors that determine if it exists. *Schneckloth* dealt with consent to a search in a criminal case, but lower courts have used the totality of the circumstances approach when ruling on deciding the voluntariness of consent given for drug testing.[26] Courts reviewing consent in public employee drug testing cases have defined coercion as the threat of job loss or demotion if an employee refuses to submit to testing.[27]

According to the Supreme Court's opinion in *Schneckloth*, the presence of coercion depends on the following factors.

Environment. Pre-initial-appearance testing usually occurs in a detention facility. The Supreme Court has noted that custody alone is not coercive but does increase the government's burden of proving that consent is voluntary.[28] Features may exist in a custodial setting to heighten coercion. For example, release from custody tied to consent to drug testing, either explicit or implicit, would reduce voluntariness. The custodial setting also may heighten the effect of certain individual factors that may reduce an arrestee's understanding of consent.

Maturity. Courts have ruled that maturity largely depends on an individual's age and education, but they have not set a definitive age or education level where maturity exists.[29] However, programs should note the emphasis on age and education when determining maturity and take special care when approaching younger arrestees.

Maturity also can depend on an arrestee's prior involvement with the legal system. The Supreme Court has used in its totality-of-the-circumstances test the fact that a consenting individual was "no newcomer to the law."[30] A Federal appeals court, noting a subject's two previous convictions, ruled in 1983 that he voluntarily consented to a search of his home.[31]

Mental incapacitation and "knowing" consent. Some mentally impaired arrestees may not understand the concept of voluntary consent. Other arrestees may be incapacitated by substance abuse. This can be a temporary impairment or a long-term disability affecting an arrestee's release.

The Supreme Court did not make knowledge of the right to refuse consent a prerequisite for valid consent.[32] However, proof that an arrestee knew of his right to refuse can help prove that consent was voluntary, especially in a coercive environment.[33] Drug testing programs should give an explanation of the drug test, especially if it cannot remove arrestees from the general population for testing.

Meeting Legal Requirements

This monograph has attempted to outline procedures that will most likely satisfy possible legal requirements for pretrial drug testing. The major procedures include the following.

Defining legal requirements. Before undertaking drug testing, program administrators should consult their jurisdiction's attorney for an opinion concerning pretrial drug testing. The Multnomah County pretrial program did this, and the county's counsel raised several important issues such as whether drug testing was a reasonable search and whether individualized suspicion was required when testing defendants. Administrators may also ask the attorney for a review of the principal Supreme Court rulings on drug testing: *Skinner* v. *Railway Labor Executives Association*, 489 U.S. 602 (1989) and *National Treasury Employees' Union* v. *Von Raab*, 489 U.S. 656 (1989).

Recommending defendants for pretrial drug monitoring. If other courts follow the requirements for reasonableness outlined in the *Berry* decision, pretrial drug testing programs will have to show that defendants recommended for pretrial drug monitoring would otherwise be likely to continue using drugs. One possible way of doing this is to include drug use information in an overall "drug risk assessment." The Pima County program used a drug use assessment profile that includes age, prior failure to appear for court, and current drug charges as factors. The Multnomah County program recommends defendants for pretrial drug monitoring by reviewing indications of drug use such as self-admitted drug use, current and prior drug charges, and drug use information from references and probation and parole officers.

Obtaining consent to pre-initial-appearance testing. The demonstration programs performing pre-initial-appearance testing screened out arrestees who—because of language, mental capacity, or incapacitation—might not understand the concept of consent, and tested only remaining defendants who submit voluntarily. The screening techniques mirrored those used to screen for the pretrial interview. When possible, programs removed arrestees from the general custodial setting to a more private area.

All pretrial drug testing programs should give defendants a verbal and written explanation of the drug test. Staff should explain that the test is voluntary, that the court will use test information to set release conditions or in other bond-related matters (such as bond revocation hearings), that the court will not use results to determine guilt, and that scheduled drug tests may become a release condition if the initial test is positive. Staff should also state that the arrestee can refuse to submit to testing and still be considered for pretrial release. Exhibit 10–1 is an example of a written explanation.

Exhibit 10–1

Sample of a Written Explanation

By signing this form, I agree to provide a urine specimen to Pretrial Services. I have been informed verbally of the following:

1) My participation in drug testing is voluntary. I may refuse to provide a urine sample and still be eligible for pretrial release.
2) The results of my drug test and information from my pretrial interview will be used by the court to set the conditions of my release. The results will not be used as evidence against me in this or any other case nor will the test results be used to bring new charges against me.
3) The court may order drug testing as a condition of pretrial release if this test is positive.
4) If I fail to report for drug testing as required, or fail to abide by any condition of pretrial release, the court may revoke my release.

Defendant's Signature

Case Number

Collector's Signature

Date

Both the written and oral notices are identical and in the language the arrestee best understands. The program may wish to give the defendant a hardcopy of the signed consent form.

Ensuring privacy of specimen collection. Most of the demonstration drug testing programs attempted to ensure as private a collection atmosphere as possible. For example, the TASC (Treatment Alternatives to Street Crime) laboratory in Maricopa County used a

two-way mirror system to observe specimen submission during pretrial drug monitoring. The defendant went into the rest room alone and was observed through the mirror by a TASC collector.

Adopting acceptable chain of custody procedures. Each demonstration program developed policies for chain of custody, specifically urine collection and specimen testing, similar to those outlined in Chapter IV, Chain Of Custody. Each used a legally acceptable technology to perform initial tests and either retested or confirmed positive results. All had policies for observing urine submission, properly labeling specimens, and transporting samples from the collection area to the laboratory.

Summary of Major Points

- Drug testing is a search under the fourth amendment.
- Lower courts have ruled that drug testing complies with substantive due process when collection and testing procedures are reasonable.
- No court has yet determined that pretrial drug testing affects the right to equal protection of the law. In the future, however, pretrial drug testing programs may have to show that defendants recommended for pretrial drug monitoring would otherwise be likely to continue using drugs.
- Drug testing programs should provide a verbal and written explanation of the drug test before requesting the arrestee's consent.
- Before undertaking drug testing, program administrators should consult their jurisdiction's attorney for an opinion.

Notes

1. *Berry* v. *District of Columbia*, 833 F. 2d 1031 (D.C. Cir., 1987).

2. U.S. Const. Amend. IV.

3. *Bell* v. *Wolfish*, 441 U.S. 520, 559 (1979); *O'Connor* v. *Ortega*, 480 U.S. 709, 721 (1987); *New Jersey* v. *TLO*, 469 U.S. 324, 341 (1985); and *U.S.* v. *Martinez-Fuerte*, 428 U.S. 543, 560 (1976). Individualized suspicion states that a search may be conducted if an individual's conduct provides a reasonable basis for the search. Usually, the intrusion into privacy must be minimal (*Terry* v. *Ohio*, 392 U.S. 1 [1968]). In its opinions in *Skinner* v. *Railway Labor Executives Association*, 489 U.S. 602 (1989) and *National Treasury Employees' Union* v. *Von Raab*, 489 U.S. 656 (1989), the Supreme Court added to this balancing test a special needs search focused on individuals. A special needs search occurs when there is only a minimal intrusion into privacy but an important government interest outside of normal law enforcement. Individualized suspicion is unnecessary since requiring it would jeopardize that interest (*Martinez-Fuerte*, 428 U.S. 543, 560; *Skinner*, 489 U.S. 602, 634–633; and *NTEU*, 489 U.S. 656, 668–672). The Court ruled that urinalysis performed on public employees in the interest of public safety fell under the special needs search category. To date, however, the special needs test for reasonableness has not been applied to criminal justice drug testing.

4. *Skinner*, 489 U.S. 602, and *NTEU*, 489 U.S. 656.

5. *Berry*, 833 F. 2d 1031.

6. Id, 1035–1036.

7. The D.C. and Prince George's County programs test all arrestees charged with criminal offenses, as did the Milwaukee County program. The Maricopa and Los Angeles County programs tested all felony arrestees. Before discontinuing pre-initial-appearance testing, the Multnomah and Pima County programs tested all felony arrestees.

8. In *Berry*, the Appeals Court considered the government's desire to reduce pretrial misconduct among drug-using arrestees valid enough to conduct pretrial drug monitoring but noted that its opinion did not address pre-initial-appearance testing (*Berry*, 1033 and 1036, n. 20). As in the degree of privacy maintained by pretrial arrestees before bond is set, whether the desire to reduce pretrial misconduct can be applied to pre-initial-appearance testing may be a question for individual courts to decide.

9. See *Skinner* and *NTEU* supra. n. 4.

10. *NTEU*, 489 U.S. 656, 678; the Customs Agency's testing program covered such staff positions as accountant, baggage clerk, co-op student, and mail clerk/assistant. The Court doubted that persons in these jobs would have access to classified information and asked the Appeals Court to review the work categories that fell under the testing program.

11. *Berry*, 833 F. 2d 1031, 1035.

12. *Matthews* v. *Eldridge*, 424 U.S. 319, 335 (1976).

13. *Rochin* v. *California*, 342 U.S. 165, 172 (1952).

14. Self-incrimination is not an issue since urinalysis yields physical evidence which is not covered under the fifth amendment (*Schmerber* v. *California*, 384 U.S. 757, 761 [1966]). Moreover, urinalysis results are considered pretrial program information, which cannot be used to determine guilt. To further control how test results are used, the major criminal justice representatives in each of the current testing jurisdictions, particularly the chief judge of the local court, the local prosecutor, and public defender, signed a Memorandum of Understanding which, in part, stated that test results would not be used on the question of guilt.

15. Brief for the Appellate, *Berry* v. *District of Columbia* at 1. This view is based on the Supreme Court's decision in *Rochin*, 342 U.S. 165. In that case, the court ruled that police action in attempting to extract morphine pills from an arrestee, first by attempting to extract them from his mouth and then through pumping his stomach against his will, was behavior that "shocks the conscience" and violates the fifth amendment's due process clause. Id, 172, 174.

16. *Schmerber*, 384 U.S. 757, 768–771.

17. *Yanez* v. *Romero*, 619 F. 2d 851, 854 (10th Cir., 1980), and *Feliciano* v. *City of Cleveland*, 661 F. Supp. 578, 586 (N.D. Ohio, 1987).

18. *National Treasury Employees' Union* v. *Von Raab*, 816 F. 2d 170, 181 (5th Cir., 1987), and *Capua* v. *City of Plainfield*, 643 F. Supp. 1507, 1521 (D.N.J., 1986).

19. *Capua*, 643 F. Supp. 1507, and *Jones* v. *McKenzie*, 628 F. Supp. 1500 (D.D.C., 1986).

20. *NTEU*, 816 F. 2d. 170, 181.

21. The Washington, D.C., and Federal pretrial programs use EMIT, as did the Maricopa, Multnomah, and Milwaukee programs. The Pima and Prince George's programs used Fluorescent Polarization Immunoassay (FPIA); the Prince George's County program has since switched to EMIT. The Los Angeles County program uses Radioimmunoassay technique (RIA).

22. *Peranzo* v. *Coughlin*, 675 F. Supp. 102 (S.D.N.Y., 1987), urinalysis as the only evidence at prison disciplinary and parole hearings satisfies due process; *Jensen* v. *Lick*, 589 F. Supp. 35 (D.N.D., 1984), unconfirmed EMIT test does not violate due process; *Wykoff* v. *Resig*, 613 F. Supp. 1504 (N.D. Ind., 1985), double EMIT tests or their equivalent satisfy due process; and *U.S.* v. *Jones*, No. 83–31 (D.C. Ct. App., 1988), retests on EMIT satisfy procedural due process in impeaching defendant's testimony at trial.

23. Brief for the Appellant, *Berry* v. *District of Columbia*, 833 F. 2d 1031, 17. Future rulings on equal protection might hinge on whether the government's interest in reducing pretrial misconduct among drug users is strong enough to test only certain arrestees.

24. *Schneckloth*, 412 U.S. 218, 219 (1973); *U.S.* v. *Mendenhall*, 446 U.S. 544, 558–559 (1979); and *U.S.* v. *Watson*, 423 U.S. 411, 424 (1976).

25. *Mack* v. *U.S.*, 814 F. 2d 120, 124 (2nd Cir., 1987).

26. *Feliciano* v. *City of Cleveland*, 661 F. Supp. 578, 593 (N.D. Ohio, 1987); *Railway Executives Assn.* v. *Burnley*, 839 F. 2d 575, 589 (9th Cir., 1988); and *American Federation of Government Employees* v. *Weinberger*, 651 F. Supp. 726, 736 (S.D. Ga., 1986).

27. *Capua*, 643 F. Supp. 1507, 1521; *Feliciano*, 661 F. Supp. 578, 595; and *AFGE*, 651 F. Supp. 726, 736. Courts have accepted consent as a condition of assignment to a new job (*NTEU*, 816 F. 2d 170, 179) and consent given on the promise that no criminal charges would be filed against the employee tested (*Mack*, 814 F. 2d 120, 124).

28. *Watson*, 423 U.S. 411, 424.

29. *U.S.* v. *Calvente*, 722 F. 2d 1019 (2nd Cir., 1983), stressing defendant's age and prior involvement with the law; and *U.S.* v. *Mayes*, 552 F. 2d 729 (6th Cir., 1977), consent invalid when given by an 18-year-old defendant with less than a seventh-grade education.

30. *Watson*, 423 U.S. 411, 424. The subject in this case had consented to a search of his car for stolen credit cards. The Court noted a prior arrest on mail theft charges and the arrestee's prior cooperation with law enforcement officials in the 2 years preceding its ruling.

31. *Calvente*, 722 F. 2d 1019, 1023.

32. *Schneckloth*, 412 U.S. 218, 227: "While knowledge of the right to refuse consent is one factor to be taken into account (in determining whether consent is voluntary), the government need not establish such knowledge as the *sine qua non* of an effective search"; and *Watson*, 423 U.S. 411.

33. *Schneckloth*, 412 U.S. 218; *Mendenhall*, 446 U.S. 544, 558–559; and *U.S.* v. *Bethea*, 598 F. 2d 331 (4th Cir., 1979).

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Appendix A: 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records; Final Rule

SUBCHAPTER A—GENERAL PROVISIONS

PART 1—[RESERVED]

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

Subpart A—Introduction

Subpart B—General Provisions

Subpart C—Disclosures With Patient's Consent

Subpart D—Disclosures Without Patient Consent

Subpart E—Court Orders Authorizing Disclosures and Use

AUTHORITY: Sec. 408 of Pub. L. 92-255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub. L. 93-282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94-237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94-581, 90 Stat. 2852; sec. 509 of Pub. L. 96-88, 93 Stat. 695; sec. 973(d) of Pub. L. 97-35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98-24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290ee-3) and sec. 333 of Pub. L. 91-616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93-282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94-581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98-24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290dd-3).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

Subpart A—Introduction

§ 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98-24 to section 527 of the Public Health Service Act which is codified at 42 U.S.C. 290ee-3. The amended statutory authority is set forth below:

§ 290ee-3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not nore than $5,000 in the case of each subsequent offense.

(g) *Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol

abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98-24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd-3. The amended statutory authority is set forth below:

§ 290dd-3. CONFIDENTIALITY OF PATIENT RECORDS

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces,

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) *Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94-581. The responsibil-

ity of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

§ 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to § 2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee-3(f), 42 U.S.C. 290dd-3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers* v. *United States*, 327 U.S. 614, 621-22, 66 S. Ct. 705, 707-08 (1946)).

§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee-3(f) and 42 U.S.C. 290dd-3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

§ 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient indentifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the re-

quest of a law enforcement agency or official: and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

Person means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

Program means a person which in whole or in part holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment. For a general medical care facility or any part thereof to be a program, it must have:

(a) An identified unit which provides alcohol or drug abuse diagnosis, treatment, or referral for treatment or

(b) Medical personnel or other staff whose primary function is the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment and who are identified as such providers.

Program director means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

Qualified service organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the progams, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

§ 2.12 Applicability.

(a) *General—(1) Restrictions on disclosure.* The restrictions on disclosure

in these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee-3(c), 42 U.S.C. 290dd-3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administraton provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

(i) Within a program or

(ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

(i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

(i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;

(ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under § 2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with § 2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms "patient" and "program" are defined in § 2.11) if the program is federally assisted in any manner described in § 2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation pro-

grams, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment.

(2) *Federal assistance to program required.* If a patient's alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under § 2.12(b), that patient's record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in § 2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by these regulations unless the program itself received Federal assistance as defined by § 2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under § 2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgement of the presence of an identified patient in a facility or part of a facility if the facility is not publicy identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgement does not

reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

§ 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors*—(1) *Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients*—(1) *Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: "Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]"; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These "research privilege" statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilage granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon threreafter as the patient is capable of rational communication, each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

(5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser *Unless:*

(1) The patient consents in writing;

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.)

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance

on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) ☐ Request ☐ Authorize:
2. (name or general designation of program which is to make the disclosure)

3. To disclose: (kind and amount of information to be disclosed)

4. To: (name or title of the person or organization to which disclosure is to be made)

5. For (purpose of the disclosure)

6. Date (on which this consent is signed)

7. Signature of patient

8. Signature of parent or guardian (where required)

9. Signature of person authorized to sign in lieu of the patient (where required)

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired:

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

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§ 2.32 Prohibition on redisclosure.

Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Definitions.* For purposes of this section:

Central registry means an organization which obtains from two or more member progams patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse

physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

Maintenance treatment means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Member program means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information:

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of § 2.31, except that:

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole offi-

cers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(2) The name of the individual making the disclosure;

(3) The date and time of the disclosure; and

(4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research;

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and

(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:

(i) The rights and welfare of patients will be adequately protected; and

(ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

§ 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a peer review organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in § 2.11, program includes an employee of, or provider of medical services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a peer review organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66 of these regulations.

Subpart E—Court Orders Authorizing Disclosure And Use

§ 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee-3, 42 U.S.C. 290dd-3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

(1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;

(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or

(3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it ap-

pears that the patient records are needed to provide evidence. An application mst use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrunity.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons: and

(2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order.

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.66 is sought with an order under this section, the person holding the records must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the applica-

tion shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity

to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of § 2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information.* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65 of these regulations.

§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 2.65 of these regulations.

PART 2a—PROTECTION OF IDENTITY—RESEARCH SUBJECTS

Sec.

Sec.
2a.6 Issuance of Confidentiality Certificates; single project limitation.
2a.7 Effect of Confidentiality Certificate.
2a.8 Termination.

AUTHORITY: Sec. 3(a), Pub. L. 91-513 as amended by sec. 122(b), Pub. L. 93-282; 84 Stat. 1241 (42 U.S.C. 242a(a)), as amended by 38 Stat. 132.

SOURCE: 44 FR 20384, Apr. 4, 1979, unless otherwise noted.

§ 2a.1 Applicability.

(a) Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) provides that "[t]he Secretary [of Health and Human Services] may authorize persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals." The regulations in this part establish procedures under which any person engaged in research on mental health including research on the use and effect of alcohol and other psychoactive drugs (whether or not the research is federally funded) may, subject to the exceptions set forth in paragraph (b) of this section, apply for such an authorization of confidentiality.

(b) These regulations do not apply to:

(1) Authorizations of confidentiality for research requiring an Investigational New Drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or to approved new drugs, such as methadone, requiring continuation of long-term studies, records, and reports. Attention is called to 21 CFR 291.505(g) relating to authorizations of confidentiality for patient records maintained by methadone treatment programs.

(2) Authorizations of confidentiality for research which are related to law enforcement activities or otherwise within the purview of the Attorney General's authority to issue authorizations of confidentiality pursuant to section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) and 21 CFR 1316.21.

(c) The Secretary's regulations on confidentiality of alcohol and drug abuse patient records (42 CFR part 2) and the regulations of this part may, in some instances, concurrently cover the same transaction. As explained in 42 CFR 2.24 and 2.24-1, 42 CFR part 2 restricts voluntary disclosures of information from applicable patient records while a Confidentiality Certificate issued pursuant to the regulations of this part protects a person engaged in applicable research from being compelled to disclose identifying characteristics of individuals who are the subject of such research.

§ 2a.2 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(b) *Person* means any individual, corporation, government, or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(c) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

(d) *Drug* has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(e) *Controlled drug* means a drug which is included in schedule I, II, III, IV, or V of part B of the Controlled Substances Act (21 U.S.C. 811-812).

(f) *Administer* refers to the direct application of a drug to the body of a human research subject, whether such application be by injection, inhalation, ingestion, or any other means, by (1) a qualified person engaged in research (or, in his or her presence, by his or her authorized agent), or (2) a re-

search subject in accordance with instructions of a qualified person engaged in research, whether or not in the presence of a qualified person engaged in research.

(g) *Identifying characteristics* refers to the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.

(h) *Psychoactive drug* means, in addition to alcohol, any drug which has as its principal action an effect on thought, mood, or behavior.

§ 2a.3 Application; coordination.

(a) Any person engaged in (or who intends to engage in) the research to which this part applies, who desires authorization to withhold the names and other identifying characteristics of individuals who are the subject of such research from any person or authority not connected with the conduct of such research may apply to the Office of the Director, National Institute on Drug Abuse, the Office of the Director, National Institute of Mental Health, or the Office of the Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857 for an authorization of confidentiality.

(b) If there is uncertainty with regard to which Institute is appropriate or if the research project falls within the purview of more than one Institute, an application need be submitted only to one Institute. Persons who are uncertain with regard to the applicability of these regulations to a particular type of research may apply for an authorization of confidentiality under the regulations of this part to one of the Institutes. Requests which are within the scope of the authorities described in § 2a.1(b) will be forwarded to the appropriate agency for consideration and the person will be advised accordingly.

(c) An application may accompany, precede, or follow the sumission of a request for DHHS grant or contract assistance, though it is not necessary to request DHHS grant or contract assistance in order to apply for a Confidentiality Certificate. If a person has previously submitted any information required in this part in connection with a DHHS grant or contract, he or she may substitute a copy of information thus submitted, if the information is current and accurate. If a person requests a Confidentiality Certificate at the same time he or she submits an application for DHHS grant or contract assistance, the application for a Confidentiality Certificate may refer to the pertinent section(s) of the DHHS grant or contract application which provide(s) the information required to be submitted under this part. (See §§ 2a.4 and 2a.5.)

(d) A separate application is required for each research project for which an authorization of confidentiality is requested.

§ 2a.4 Contents of application; in general.

In addition to any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project shall contain:

(a) The name and address of the individual primarily responsible for the conduct of the research and the sponsor or institution with which he or she is affiliated, if any. Any application from a person affiliated with an institution will be considered only if it contains or is accompanied by documentation of institutional approval. This documentation may consist of a written statement signed by a responsible official of the institution or of a copy of or reference to a valid certification submitted in accordance with 45 CFR part 46.

(b) The location of the research project and a description of the facilities available for conducting the research, including the name and address of any hospital, institution, or clinical laboratory facility to be utilized in connection with the research.

(c) The names, addresses, and summaries of the scientific or other appropriate training and experience of all personnel having major responsibilities in the research project and the training and experience requirements for major positions not yet filled.

§ 2a.5 Contents of application; research projects in which drugs will be administered.

(a) In addition to the information required by § 2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

(2) Evidence that individuals who administer drugs are authorized to do so under applicable Federal and State law; and

(3) In the case of a controlled drug, a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

(b) An application for an authorization of confidentiality with respect to a research project which involves the administering of a controlled drug may include a request for exemption of persons engaged in the research from State or Federal prosecution for possession, distribution, and dispensing of controlled drugs as authorized under section 502(d) of the Controlled Substances Act (21 U.S.C. 872(d)) and 21 CFR 1316.22. If the request is in such form, and is supported by such information, as is required by 21 CFR 1316.22, the Secretary will forward it, together with his or her recommendation that such request be approved or disapproved, for the consideration of the Administrator of the Drug Enforcement Administration.

§ 2a.6 Issuance of Confidentiality Certificates; single project limitation.

(a) In reviewing the information provided in the application for a Confidentiality Certificate, the Secretary will take into account:

(1) The scientific or other appropriate training and experience of all personnel having major responsibilities in the research project;

(2) Whether the project constitutes bona fide "research" which is within the scope of the regulations of this part; and

(3) Such other factors as he or she may consider necessary and appropriate. All applications for Confidentiality Certificates shall be evaluated by the Secretary through such officers and employees of the Department and such experts or consultants engaged for this purpose as he or she determines to be appropriate.

(b) After consideration and evaluation of an application for an authorization of confidentiality, the Secretary will either issue a Confidentiality Certificate or a letter denying a Confidentiality Certificate, which will set forth the reasons for such denial, or will request additional information from the person making application. The Confidentiality Certificate will include:

(1) The name and address of the person making application;

(2) The name and address of the individual primarily responsible for conducting the research, if such individual is not the person making application;

(3) The location of the research project;

(4) A brief description of the research project;

(5) A statement that the Certificate does not represent an endorsement of the research project by the Secretary;

(6) The Drug Enforcement Administration registration number for the project, if any; and

(7) The date or event upon which the Confidentiality Certificate becomes effective, which shall not be before the later of either the commencement of the research project or the date of issuance of the Certificate, and the date or event upon which the Certificate will expire.

(c) A Confidentiality Certificate is not transferable and is effective only with respect to the names and other identifying characteristics of those individuals who are the subjects of the single research project specified in the Confidentiality Certificate. The recipient of a Confidentiality Certificate shall, within 15 days of any completion or discontinuance of the research project which occurs prior to the expiration date set forth in the Certificate, provide written notification to the Di-

rector of the Institute to which application was made. If the recipient determines that the research project will not be completed by the expiration date set forth in the Confidentiality Certificate he or she may submit a written request for an extension of the expiration date which shall include a justification for such extension and a revised estimate of the date for completion of the project. Upon approval of such a request, the Secretary will issue an amended Confidentiality Certificate.

(d) The protection afforded by a Confidentiality Certificate does not extend to significant changes in the research project as it is described in the application for such Certificate (e.g., changes in the personnel having major responsibilities in the research project, major changes in the scope or direction of the research protocol, or changes in the drugs to be administered and the persons who will administer them). The recipient of a Confidentiality Certificate shall notify the Director of the Institute to which application was made of any proposal for such a significant change by submitting an amended application for a Confidentiality Certificate in the same form and manner as an original application. On the basis of such application and other pertinent information the Secretary will either:

(1) Approve the amended application and issue an amended Confidentiality Certificate together with a Notice of Cancellation terminating original the Confidentiality Certificate in accordance with § 2a.8; or

(2) Disapprove the amended application and notify the applicant in writing that adoption of the proposed significant changes will result in the issuance of a Notice of Cancellation terminating the original Confidentiality Certificate in accordance with § 2a.8.

§ 2a.7 Effect of Confidentiality Certificate.

(a) A Confidentiality Certificate authorizes the withholding of the names and other identifying characteristics of individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances:

(1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information,

(2) Authorized personnel of DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHHS personnel), or

(3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

§ 2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See § 2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

PART 3—NATIONAL CENTER FOR HEALTH STATISTICS; SPECIAL STATISTICAL SERVICES

Sec.

AUTHORITY: Sec. 3, 49 Stat. 293, as amended; 15 U.S.C. 192a, Reorg. Plan No. 2 of 1946, 11 FR 7873, 60 Stat. 1095, Reorg. Plan No. 1 of 1953, 18 FR 2053, 63 Stat. 631; 3 CFR 1943-1948 Comp.

§ 3.1 Authorization for special statistical services.

Upon the receipt of a written request by any person, firm or corporation the Director of the National Center for Health Statistics may furnish special statistical services if he determines that: (a) The services requested are within the scope of authorized activities of the center, (b) facilities necessary for the performance of the services are available, (c) the performance of such services will not interfere with the performance of the regular duties of the Center, and (d) the data or statistics requested are not confidential.

[27 FR 3739, Apr. 19, 1962]

§ 3.2 Charges for special statistical services.

The Director of the National Center for Health Statistics will establish a charge for each authorized special statistical service which shall be based on the estimated cost of the service. No services will be undertaken prior to the prepayment of the estimated cost or of such portion of the estimated cost as the Director may require. Adjustments in the prepaid charge resulting in a refund to the requesting party or a further billing by the Center may be made at any time during the progress of the services or upon their completion if necessary to reflect the actual cost of the services.

[27 FR 3739, Apr. 19, 1962]

PART 4—NATIONAL LIBRARY OF MEDICINE

Sec.

AUTHORITY: 42 U.S.C. 216, 286.

SOURCE: 56 FR 29188, June 26, 1991, unless otherwise noted.

§ 4.1 Programs to which these regulations apply.

(a) The regulations of this part govern access to the National Library of Medicine's facilities and library collections and the availability of its bibliographic, reproduction, reference, and related services. These functions are performed by the Library directly for the benefit of the general public and health-sciences professionals as required by sections 465(b) (3)-(6) of the Act (42 U.S.C. 286(b) (3)-(6)).

(b) The regulations of this part do not apply to:

(1) The Library's internal functions relating to the acquisition and preservation of materials and the organization of these materials as required by

sections 465(b) (1) and (2) of the Act (42 U.S.C. 286(b) (1) and (2)).

(2) The availability of "records" under the Freedom of Information Act or the Privacy Act of 1974 (5 U.S.C. 552, 552a). These matters are covered in 45 CFR parts 5 and 5b.

(3) Federal assistance for medical libraries and other purposes which are authorized by sections 469–477 of the Act (42 U.S.C. 286b to 286b–8). (See parts 59a, 61 and 64 of this chapter.)

(4) The availability of facilities, collections, and related services of Regional Medical Libraries established or maintained under the authority in section 475 of the Act (42 U.S.C. 286b–6). (See part 59a, subpart B of this chapter.)

§ 4.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

Collections means all books, periodicals, prints, audiovisual materials, films, videotapes, recordings, manuscripts, and other resource materials of the library. It does not include data processing tapes or programs used solely for internal processing activities to generate reference materials, nor does it include "records" of the Library as defined in 45 CFR 5.5. Records of the Library are available in accordance with the regulations under the Freedom of Information Act and Privacy Act of 1974. (See 45 CFR parts 5 and 5b.)

Director means the Director of the National Library of Medicine or the Director's delegate.

Health-sciences professional means any person engaged in: (1) The administration of health activities; (2) the provision of health services; or (3) research, teaching, or education concerned with the advancement of medicine or other sciences related to health or improvement of the public health.

Historical collection means: (1) Materials in the collections published or printed prior to 1914; (2) manuscripts and prints; (3) the archival film collection; and (4) other materials of the collections which, because of age, or unique or unusual value, require special handling, storage, or protection for their preservation, as determined by the Director.

Library means the National Library of Medicine, established by section 465 of the Act (42 U.S.C. 286).

Regional Medical Library means a medical library established or maintained as a regional medical library under section 475 of the Act (42 U.S.C. 286b–6).

§ 4.3 Purpose of the Library.

The purpose of the Library is to assist the advancement of medical and related sciences and aid the dissemination and exchange of scientific and other information important to the progress of medicine and the public health. The Library acquires and maintains library materials pertinent to medicine, including audiovisual materials; compiles, publishes, and disseminates catalogs, indices, and bibliographies of these materials, as appropriate; makes available materials, through loan or otherwise; provides reference and other assistance to research; and engages in other activities in furtherance of this purpose.

§ 4.4 Use of Library facilities.

(a) *General.* The Library facilities are available to any person seeking to make use of the collections. The Director may prescribe reasonable rules to assure the most effective use of facilities by health-sciences professionals and to protect the collections from misuse or damage. These rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination.

(b) *Reading rooms.* Public reading rooms are available for obtaining and reading materials from the collections. The Director may prescribe reasonable rules designed to provide adequate reading space and orderly conditions and procedures.

(c) *Study rooms.* Upon request a limited number of study rooms may be made available to individuals requiring extensive use of Library materials. Requests for study rooms shall be addressed in writing to the Director. The Director shall give priority, in the following order, for study room use to:

Appendix B: A Comparison of Urinalysis Technologies For Drug Testing in Criminal Justice (Research in Action)

U.S. Department of Justice
Office of Justice Programs
National Institute of Justice

NATIONAL INSTITUTE OF JUSTICE
Research in Action

Charles B. DeWitt, Director

June 1991

A Comparison of Urinalysis Technologies for Drug Testing in Criminal Justice

by Christy Visher and Karen McFadden

Need for the study

It was once widely believed that drug users engaged primarily in minor property crimes to finance their habits. Recent research, however, indicates that the links between drugs and crime go well beyond minor theft. In fact, data from the National Institute of Justice's Drug Use Forecasting (DUF) Program in 1990 show that a majority of persons charged with serious property offenses and most types of violent crime test positive for illegal drugs at arrest. Moreover, several studies completed over the last decade indicate quite clearly that the most frequent, serious offenders are also the heaviest drug users. Surveys of State prison inmates conducted by the Bureau of Justice Statistics have found that over 40 percent of inmates report using illegal drugs on a daily or near-daily basis in the month before incarceration (see References).

Christy Visher, Ph.D., *a Senior Research Associate with the National Institute of Justice, is currently examining the relationship between drug use and criminal behavior.*

Karen McFadden, *Branch Chief, Bureau of Justice Assistance, was responsible for the study's design and implementation.*

Faced with large numbers of offenders who use illegal drugs, criminal justice officials have been using drug testing as a tool for improving decisions and reducing criminal activity. Indeed, the President's 1991 National Drug Control Strategy emphasizes drug testing through urinalysis as a priority for identifying and monitoring the drug-involved offender and encourages all States to implement offender drug testing. Criminal justice is using drug testing at a number of stages: on arrest, during the pretrial release period, in jails and prisons, and during probation and parole.

Given the expanded use of drug testing in the criminal justice system, practitioners need comparative information about the use and accuracy of urinalysis technologies. Agencies implementing drug testing programs may have concerns about the relative accuracy of different tests and whether accuracy varies by type of drug. Practitioners may lack unbiased information about the different types and frequency of errors occurring in drug testing. In addition, drug testing technologies may vary in ease of use, suitability for use as a screening test, and relative costs.

This report summarizes the first study to compare four commonly used urine testing technologies using specimens gathered from a criminal justice population.[1] It assumes basic knowledge about urine testing methods and procedures. For information about uses of urine tests for criminal justice populations, guidelines for conducting urine tests in criminal justice settings, and legal issues, see the list of publications at the end of this report.

Purpose of the study

The primary goal of this study is to give decisionmakers in the criminal justice system clear and concise information that will help them make informed decisions about available urinalysis technologies. The need for such information led the Bureau of Justice Assistance and the National Institute of Justice, Office of Justice Programs, U.S. Department of Justice, to formulate and jointly fund a study of the technologies used in criminal justice settings to detect illegal drugs in urine.

Urine specimens were obtained from parolees as part of ongoing supervision

[1] The full report, *A Comparison of Urinalysis Technologies for Drug Testing in Criminal Justice*, discusses the study design; describes the two basic types of urinalysis technologies, immunoassay and chromatography; presents extensive data from the study; summarizes the study's conclusions and policy recommendations; and includes references and a technical glossary.

requirements. Each sample was tested with four analytical procedures or technologies routinely used to detect drugs in urine. The study also collected urine specimens from a small group of arrestees. The results were then compared against gas chromatography/mass spectrometry (GC/MS), the most accurate method of drug detection. Analysis and comparison of test results provide answers to the following questions:

- How accurate are the technologies? Does one particular technology result in more false positive or false negative errors than others?

- Do the existing Federal guidelines for drug testing in the workplace, especially for cutoff levels, meet the needs of the criminal justice system?

- Is one technology consistently accurate enough to eliminate the need for routine confirmation by an alternative method?

- Do technologies exist that can be used by paraprofessionals in a criminal justice operational environment?

The answers to these questions will give criminal justice practitioners the detailed information they need to make informed decisions about the advantages and shortcomings of each of the technologies.

This executive summary presents the principal findings and briefly discusses some of the policy implications of the study. Interested readers can refer to the full report for a complete discussion of the study's methods and results and the implications of using urine testing technologies to detect drug use in criminal justice populations.

Study design

Five analytical procedures were used to analyze 2,668 urine specimens from parolees and arrestees; each sample was screened for opiates, cocaine, phencyclidine (PCP), amphetamines, and marijuana. The analytical procedures were EMIT™, TDx™ FPIA, Abuscreen™ RIA, standard thin-layer chromatography (TLC),[2] and gas chromatography/mass spectrometry. These procedures were chosen because they were in wide use at the time of the study. Three manufacturers of the immunoassays provided free reagents (test chemicals), test instruments, and training for the study. These manufacturers were Abbott Laboratories, manufacturers of TDx™ FPIA; Roche Diagnostic Systems, Inc., manufacturers of Abuscreen™ RIA; and Syva Company, manufacturers of EMIT™.

Laboratory technicians used GC/MS, the most sensitive and accurate of the urinalysis technologies, as the standard against which results from the four other technologies were compared. GC/MS is recognized by the drug testing industry as the preferred confirmatory technology for detecting drugs in urine.

The concentration of drugs in urine is measured in nanograms (billionths of a gram) per milliliter of liquid (ng/mL) of the drug or of the drug metabolite formed in the body as a result of the ingestion of a specific drug. The "cutoff level" is that concentration, stated in ng/mL, used to determine whether a specimen is positive or negative.

The primary study results were based on the screening and GC/MS cutoff levels specified by the National Institute on Drug Abuse (NIDA) of the U.S. Department of Health and Human Services. In two instances, different cutoff levels were used because the EMIT™ technology did not have tests available using the cutoffs in the guidelines at the time of the study (see table 1).[3]

These guidelines were formulated for Federal employee drug testing and specifically exclude drug testing in the criminal justice system; however, criminal justice agencies—along with the private sector, commercial laboratories, and manufacturers of drug testing products—have relied on the NIDA guidelines for direction in establishing and implementing drug testing programs.

If a urine specimen showed a drug present in a concentration at or above the GC/MS cutoff level established by NIDA, the sample was considered

[2] Standard thin-layer chromatography should not be confused with high-performance thin-layer chromatography (HPTLC) or toxiLab™, an onsite version of HPTLC, neither of which was examined in this study. The results obtained using standard TLC in this study cannot be generalized to the other technologies.

[3] Since the study began, Abbott Laboratories has modified some of its assays for marijuana, PCP, and amphetamines; and the products used in this study are, in some cases, no longer available. In addition, Syva Company has recently introduced a specialized assay for detecting amphetamines. It is not known how these new or modified products would compare to those used in the study.

Table 1
NIDA and Study Cutoffs for Immunoassays (Screening Tests) and GC/MS

Drug	Immunoassays	GC/MS
Marijuana	100	15
Cocaine	300	150
Phencyclidine	25[a]	25
Opiates	300	300
Amphetamines	1,000[b]	500

[a] for EMIT, 75 ng/mL
[b] for EMIT, 300 ng/mL

positive for that drug. If the GC/MS results showed a drug concentration below the cutoff, the specimen was considered negative for that drug. The test results of the four technologies were compared individually to the GC/MS results to determine their accuracy.

The study also examined the extent to which drug use may be missed in criminal justice populations. Additional analyses used cutoff levels lower than the concentrations in the NIDA guidelines to determine whether a specimen was positive or negative. Lower cutoff levels lead to more positive test results since a urine specimen containing a smaller amount of the drug would be considered positive.

All urine specimens were sent to the onsite drug testing facility operated in the Alhambra Parole Office, part of the California Department of Corrections, where technicians performed the EMIT™ and the TDx™ tests. A portion of each urine specimen was reserved and sent to BPL Toxicology Laboratory in Tarzana, California, for analysis using RIA, TLC, and GC/MS technologies. No results were shared between the onsite testing facility and the BPL Laboratory.

Study results

Accuracy of the technologies

Test results show a clear difference between the accuracy of the immunoassays as a group—EMIT™, TDx™, and RIA—and thin-layer chromatography. *Standard thin-layer chromatography performed poorly in identifying the presence of illegal drugs.*

TLC identified only 8 to 19 percent of the specimens containing opiates, cocaine, amphetamines, and PCP (in amounts at or above the NIDA cutoffs according to GC/MS) and only 48 percent of the specimens containing marijuana. All three immunoassays were more accurate than TLC. Among the immunoassays *no one type of immunoassay is consistently superior in identifying positive and negative urine specimens for the five drugs.*

A concern frequently voiced about drug testing is the possibility that the urinalysis technology being used will label as positive a urine specimen from an individual who has not used drugs. These errors are known as false positives. The study's average false positive rate, combining results for the five drug types and using the NIDA cutoff levels, was about 1 to 2 percent, based on the initial screening test, without GC/MS confirmation (see figure 1).

GC/MS confirmation of positive results from screening tests would eliminate virtually all false positive errors. However, GC/MS testing is too expensive for routine confirmation of all positive screening results in a criminal justice setting.[4]

The study also examined the extent to which the current screening technologies miss the presence of drugs in urine—that is, the extent of false negative errors. For the three immunoassays, the average false negative rate for the five drug types

[4] The study findings on false positive and false negative rates should not be the only criteria for selecting an immunoassay for use in a drug testing program. Many factors contribute to these findings and, in some cases, simply comparing the percentage of erroneous test results may be misleading. The full report discusses the study results in detail.

Confirmation test: A second test which is used to confirm positive results from an initial screening test. A confirmation test uses a different method than the screening test and provides a greater margin of certainty.

Cutoff level: The concentration of a drug in urine, usually in nanograms per milliliter (ng/mL), used to determine whether a specimen is positive (at or above the cutoff level) or negative (below the cutoff level) for the drug in question.

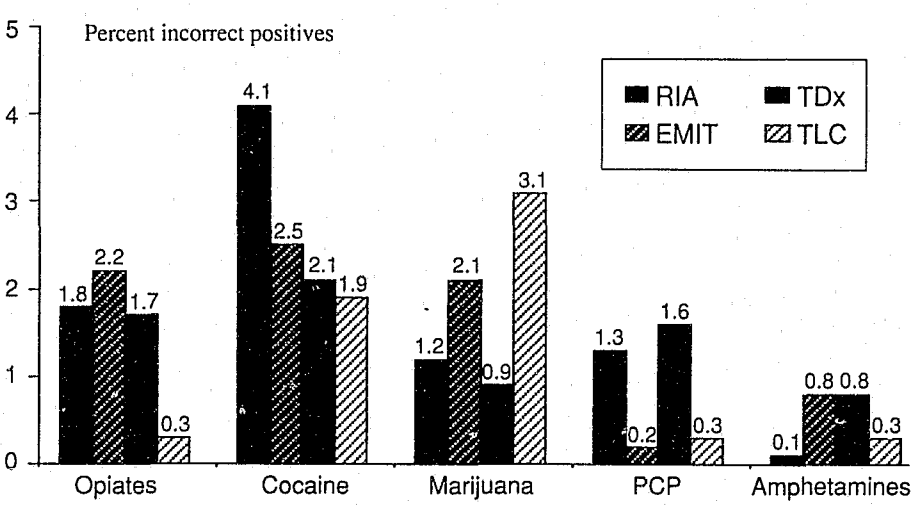
False positive: A test result indicating positive for a given drug when that drug is actually absent in a urine sample *or* present in concentrations below the designated cutoff level.

False negative: A negative test result for a given drug when that drug is present in a sample above the cutoff level for the test.

Screening test: An initial test which is used to detect drugs of abuse in urine. Screening tests are rapid and less expensive, but generally not as accurate as confirmation tests.

Figure 1

False Positive Rates* by Drug Type



*Negative by GC/MS but positive by screening test

was about 20 percent (using the NIDA screening cutoff levels in table 1). Screening tests are designed to minimize false positive results and, as a consequence, a larger number of false negative results will occur. Repeated testing of an individual on a weekly or monthly basis, however, most likely will detect illegal substances in a regular drug user.

The false negative rates for the five drugs are presented in figure 2. As the figure clearly shows, standard TLC incorrectly identified as negative a much higher proportion of urine specimens than did the three immunoassays.

The magnitude of the false negative rate was determined by the screening and confirmation cutoff levels, which followed the NIDA guidelines. A close examination of the data revealed that the immunoassay cutoffs were partly the reason for the technology's failure to identify the specimens designated as positive by GC/MS. Many of the false negative specimens contained some amount of the drug, but not at concentrations high enough for the immunoassays to label the specimen positive. Accordingly, the false negative rate would be reduced by lowering the immunoassay cutoffs.

Adequacy of current cutoff levels

A secondary objective of the study was to determine whether the current NIDA cutoff levels are appropriate for testing offenders since lower cutoff levels could lead to the detection of a greater number of drug users. To accomplish this analysis, screening and confirmation cutoffs were selected for marijuana, cocaine, and opiates that were lower than those specified by NIDA (see full report for details).

The NIDA cutoff level for screening urine specimens for marijuana is 100 ng/mL. Analysis indicated that if the cutoff levels for marijuana were lowered to 50 ng/mL, approximately *one-third more* users might be identified. Of 100 marijuana users in a group of probationers, the current standards would detect about 65 users; with the lower cutoff level, an additional 20 users might be detected.[5]

For cocaine and opiates, lowering the current NIDA screening cutoff levels to 200 ng/mL might increase detection of drug use by 10 to 20 percent.

These analyses show that some false negative test results would be considered positive if screening cutoff levels were lowered. The potential impact on drug testing programs could be considerable in the case of marijuana if more users tested positive. For cocaine or opiates, a smaller number of additional users would be identified if the cutoff levels for these drugs were lowered.

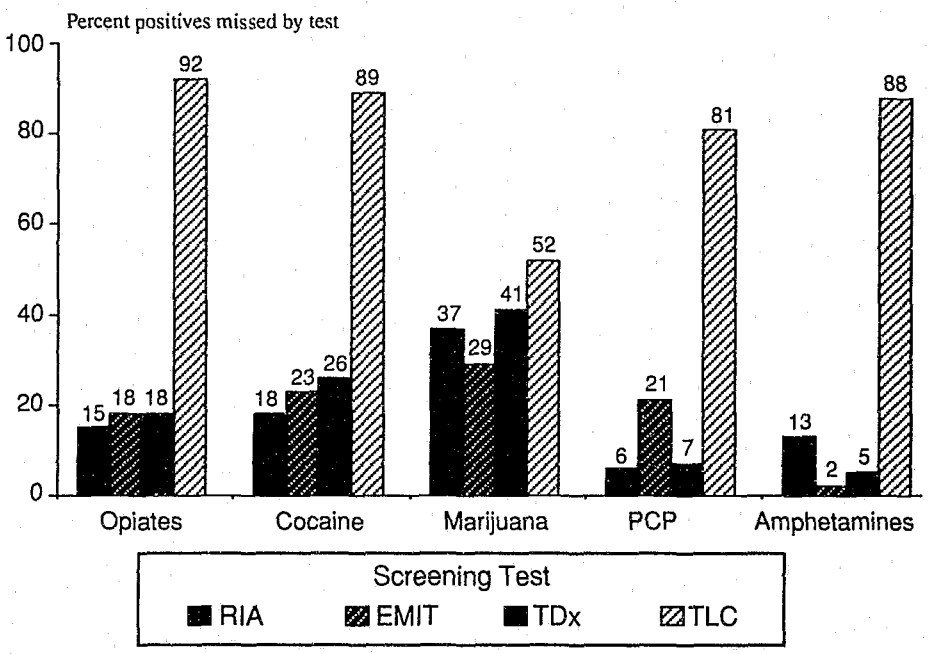
Users of urine tests must be knowledgeable about screening cutoff levels. Some criminal justice agencies may wish to use cutoff levels lower than those in the NIDA guidelines. Some manufacturers of urinalysis-based drug testing technologies allow the operator to select a cutoff level within a specified range. Others establish the cutoff level—usually that specified in the NIDA guidelines—at which a specimen is considered positive or negative.

Lowering cutoff levels would likely result in increases in the number of identified drug users. Therefore, before opting to select lower levels, criminal justice agencies must consider several issues. The possible consequences might include an increased demand for drug treatment, an increased need for additional supervision of drug-using offenders, and a greater need for jail and prison space for probation and parole revocations.

It might be argued that the cutoff levels in the NIDA guidelines are appropriate because these cutoff levels are already identifying the vast majority of drug-involved offenders in pretrial, probation, and parole testing. Moreover, in some jurisdictions, "scientifically acceptable" cutoff levels may have already been established by State law or regulation.

Figure 2

False Negative Rates* by Drug Type



*Positive by GC/MS but negative by screening test

[5]This example assumes that the concentration of marijuana metabolites in the tested population is similar to those found among individuals in this study.

At a minimum, drug testing programs in criminal justice agencies should ensure that cutoffs are set at levels that the manufacturer of the test believes to be legally defensible. The manufacturer's outlined procedures, such as preparation of reagents, should also be strictly followed to obtain maximum accuracy. Little research is available to guide the criminal justice community on how much of a given drug should be present in the urine sample before the specimen can be declared positive. Established cutoffs, such as those in the NIDA guidelines, ensure continuity of drug testing procedures among jurisdictions and uniform testing of all offenders.

The issue of confirmation

Immunoassay urinalysis technologies for drug testing are not error-free. False positive test results will occur with any immunoassay technology. In practice, of 100 negative urine specimens tested using 1 of the immunoassays examined in this study, an average of 1 or 2 specimens may test positive.

Confirmation of initial immunoassay positives by an alternate method—preferably GC or GC/MS—is recommended by the NIDA guidelines to avoid testing errors. In many criminal justice settings, officials consider as confirmation an individual's admission of drug use after being confronted with a positive drug test. If an individual contests a positive result from a screening test, however, and if that positive drug test will lead to serious punitive action, confirmation by GC/MS provides the best protection against future legal challenges. Users of urine tests must weigh the consequences of testing errors against the time and expense involved in confirming positive test results with GC/MS.

Repeat testing of urine specimens by the same method—or confirmation of screened positives using a similar technology—probably will not eliminate all erroneous results. For instance, using another type of immunoassay if the initial screen was also an immunoassay may eliminate faulty procedural results, but not the errors inherent in the technology. This repeat practice is not considered a scientific confirmatory result, but courts in some jurisdictions have allowed this type of confirmation. Any criminal justice agency considering the implementation of a drug testing program should review the relevant case law about confirmation of drug test results.

Onsite versus laboratory testing

The study results show that the two immunoassay technologies carried out by trained staff in an onsite testing facility (EMIT™ and TDx™ FPIA) are just as accurate as the immunoassay procedure performed by certified technicians in a commercial laboratory (Abuscreen™ RIA).

Although the quality of services provided by onsite testing facilities can vary greatly, many such facilities are comparable to full-service laboratories. Drug testing performed in an onsite facility using technologies designed for onsite use can be just as accurate as testing performed in a full-service laboratory. It is critical to maintain appropriate testing procedures and protocols, including chain of custody and quality control, and personnel training.

Final note

This study was designed to provide guidance on urinalysis technologies for drug testing in the criminal justice system—for arrestees, those on pretrial release, probationers, incarcerated offenders, and parolees. Some of the findings may be dependent upon the higher levels of illegal drug use in these populations than in the general population. Results should *not* be generalized to military personnel, Federal employees, pilots, railroad employees, job applicants, or other such populations. Drug testing policies for many of these groups are governed by guidelines specific to their needs.

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The Assistant Attorney General, Office of Justice Programs, coordinates the activities of the following program Offices and Bureaus: National Institute of Justice, Bureau of Justice Statistics, Bureau of Justice Assistance, Office of Juvenile Justice and Delinquency Prevention, and Office for Victims of Crime.

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