

§ 52.1070 Identification of plan.

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(c) * * *

(125) Revisions to the Maryland State Implementation Plan submitted on July 12, 1995 by the Maryland Department of the Environment:

(i) Incorporation by reference.

(A) Four letters dated July 12, 1995 from the Maryland Department of the Environment transmitting additions to Maryland's State Implementation Plan, pertaining to volatile organic compound (VOC) regulations in Maryland's air quality regulations, COMAR 26.11.

(B) Regulations:

(1) Addition of new COMAR

26.11.19.17 Control of VOC Emissions from Yeast Manufacturing, adopted by the Secretary of the Environment on October 14, 1994 and effective on November 7, 1994, revisions adopted by the Secretary of the Environment on May 12, 1995, and effective on June 5, 1995, including the following:

(j) Addition of new COMAR

26.11.19.17.A Definitions, including definitions for the terms "fermentation batch," "first generation fermenter," "stock fermenter," "trade fermenter," and "yeast manufacturing installation."

(ij) Addition of new COMAR

26.11.19.17.B Applicability, Exemptions, and Compliance Date.

(iii) Addition of new COMAR

26.11.19.17.C Requirements for Yeast Manufacturing Installations.

(iv) Addition of new COMAR

26.11.19.17.D Determination of Compliance and Testing.

(v) Addition of new COMAR

26.11.19.17.E Reporting Requirements.

(vi) Amendment to COMAR

26.11.19.17.C(3), pertaining to limits for temperature and pH.

(vii) Amendment to COMAR

26.11.19.17.D(3), pertaining to stack test dates.

(2) Addition of new COMAR

26.11.19.18 Control of VOC Emissions from Screen Printing, adopted by the Secretary of the Environment on October 14, 1994 and effective on November 7, 1994, revisions adopted by the Secretary of the Environment on May 16, 1995 and effective on June 5, 1995, including the following:

(j) Addition of new COMAR

26.11.19.18.A, including definitions for the terms "acid/etch resist ink," "anoprint ink," "back-up coating," "clear coating," "conductive ink," "electroluminescent ink," "exterior illuminated sign," "haze removal," "ink removal," "maximum VOC content," "plastic card manufacturing installation," "plywood sign coating," "screen printing," "screen printing

installation," "screen reclamation," "specialty inks."

(ii) Addition of new COMAR

26.11.19.18.B Applicability.

(iii) Addition of new COMAR

26.11.19.18.C General Requirements for Screen Printing.

(iv) Addition of new COMAR

26.11.19.18.D General Requirements for Plywood Sign Coating.

(v) Addition of new COMAR

26.11.19.18.E General Requirements for Plastic Card Manufacturing Installations.

(vi) Addition of new COMAR

26.11.19.18.F Control of VOC Emissions from the Use of Specialty Inks.

(vii) Addition of new COMAR

26.11.19.18.G Control of VOC Emissions from Clear Coating Operations.

(viii) Addition of new COMAR

26.11.19.18.H Control of VOC Emissions from Ink and Haze Removal and Screen Reclamation.

(ix) Addition of new COMAR

26.11.19.18.I.

(x) Addition of new COMAR

26.11.19.18.A(17), definition for the term "untreated sign paper."

(xi) Addition of new COMAR

26.11.19.18.C(2), replacing previous § C(2).

(xii) Addition of new COMAR

26.11.19.18.C(3) Use of Control Devices.

(xiii) Addition of new COMAR

26.11.19.18.E(2)(b), replacing previous § E(2)(b).

(xiv) Addition of new COMAR

26.11.19.18.I Record Keeping, replacing the previous § I.

(3) Addition of new COMAR

26.11.19.19 Control of VOC Emissions from Expandable Polystyrene Operations, adopted by the Secretary of the Environment on June 9, 1995, and effective on July 3, 1995, including the following:

(j) Addition of new COMAR

26.11.19.19.A Definitions.

(ij) Addition of new COMAR

26.11.19.19.B Terms Defined, including definitions for the terms "expandable polystyrene operation (EPO)," "blowing agent," "preexpander," "recycled expanded polystyrene," and "reduced VOC content beads."

(iii) Addition of new COMAR

26.11.19.19.C Applicability.

(iv) Addition of new COMAR

26.11.19.19.D General Requirements.

(v) Addition of new COMAR

26.11.19.19.E Testing Requirements.

(vi) Addition of new COMAR

26.11.19.19.F Record Keeping.

(4) Addition of new COMAR

26.11.19.21, Control of VOC Emissions from Commercial Bakery Ovens, adopted by the Secretary of the Environment on June 9, 1995, and effective on July 3, 1995.

(j) Addition of new COMAR 26.11.19.21.A Definitions.

(ii) Addition of new COMAR

26.11.19.21.B Terms Defined, including definitions for the terms "commercial bakery oven," "fermentation time," "yeast percentage," and "Yt value."

(iii) Addition of new COMAR

26.11.19.21.C Applicability and Exemptions.

(iv) Addition of new COMAR

26.11.19.21.D General Requirements.

(v) Addition of new COMAR

26.11.19.21.E Use of Innovative Control Methods.

(vi) Addition of new COMAR

26.11.19.21.F Reporting and Testing Requirements.

(ii) Additional material.

(A) Remainder of July 12, 1995 Maryland State submittals pertaining to COMAR 26.11.19.21, .17, .18, and .19.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****42 CFR Part 51**

RIN 0905-AD99

Substance Abuse and Mental Health Services Administration; Requirements Applicable to Protection and Advocacy of Individuals with Mental Illness; Final Rule

AGENCY: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: On December 14, 1994, the Department of Health and Human Services (Department or HHS) published a Notice of Proposed Rulemaking to comply with the requirements of section 116 of the Protection and Advocacy for Mentally III Individuals Act of 1986 (Act) (42 U.S.C. 10801 *et seq.*) which required that the Secretary promulgate regulations for the implementation of authorized activities of Protection and Advocacy (P&A) Systems to protect and advocate the rights of individuals with mental illness. The Department is issuing this final rule to implement Titles I and III of the Act.

These regulations will govern activities carried out by the P&A systems under the Act. The rule includes: definitions; basic

requirements regarding determination of, eligibility for and use of allotments, grant administration, eligibility for protection and advocacy services, annual and financial status reports, and remedial actions; and requirements regarding program administration, priorities, the conduct of P&A activities, access of the P&As to residents, facilities and records and confidentiality.

DATES: Effective Date: This regulation is effective November 14, 1997 except for the information collection requirements in sections 51.8, 51.10, 51.23 and 51.25. These sections will become effective upon approval under the Paperwork Reduction Act. A notice of approval will appear in the **Federal Register**.

Comments: The Department is soliciting comments on one particular section as described under section 51.22(2) in the preamble relating to representation on the governing board. To ensure consideration, comments must be submitted on or before December 15, 1997 to: Director, Center for Mental Health Services, 5600 Fishers Lane, Room 15-105, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Carole Schauer, Program Officer, Protection and Advocacy for Individuals with Mental Illness Program, Center for Mental Health Services, 5600 Fishers Lane, Room 15C-26, Rockville, Maryland 20857; telephone (301) 443-3667 (Voice), (301) 443-9006 (TTY). These are not toll-free numbers. This document is available in accessible formats (cassette tape, braille, large print or computer disk) upon request at the Center for Mental Health Services (CMHS) Knowledge Exchange Network (KEN) at (800) 789-2647 or <http://www.mentalhealth.org/>.

SUPPLEMENTARY INFORMATION:

Program History

In 1975, HHS established a program pursuant to Part C of the Developmental Disabilities Assistance and Bill of Rights Act (DD Act) (42 U.S.C. 6041, *et seq.*), providing formula grant support to the Protection and Advocacy Systems designated by each State to protect and advocate the rights of persons with developmental disabilities. This program is presently administered by the Administration on Developmental Disabilities (ADD), in the Administration on Children and Families.

Since 1986 the Department has provided additional formula grant funds to the same State-designated P&A systems to protect and advocate the rights of individuals with mental illness pursuant to the Act, as amended. The

1988 Amendments changed all references to "mentally ill individuals" in the Act to read "individuals with mental illness," but did not change the name of the Act itself. For purposes of this regulation, the program is referred to as Protection and Advocacy for Individuals with Mental Illness (PAIMI). This program is administered by the Center for Mental Health Services (CMHS), Substance Abuse and Mental Health Services Administration (SAMHSA).

These regulations will govern activities carried out by the P&A systems under the Act to protect and advocate the rights of individuals with mental illness. ADD has also amended its regulations governing P&A system operations under the DD Act to implement recent amendments. To the greatest extent possible the agencies have attempted to make both sets of regulations consistent.

Segments of the regulation published by ADD on September 30, 1996 (See 51 FR 51142 (September 30, 1996)) have been incorporated into the PAIMI regulation. The Department's goal is to ensure that all facets of the P&A system administered by the Department are subject to the same requirements. The Department hopes that in making the regulations as consistent as possible (given the minor differences between the statutes), the P&A will be able to carry out their responsibilities more effectively.

This approach is consistent with methods of legal analysis as well. A basic principle of statutory construction is that where statutes govern similar substantive areas, and affect similar classes of individuals, courts often attempt to construe such statutes *in pari materia* (meaning, on like subject matter) and might interpret certain provisions of the DD Act as applying to the Act as well. According to a leading treatise:

"[The] guiding principle * * * [in determining whether statutes are *in pari materia*] is that if it is natural and reasonable to think that the understanding of members of the legislature or persons to be affected by a statute, be [sic] influenced by another statute, then a court called upon to construe the act in question should also allow its understanding to be similarly influenced." Sutherland Stat. Const. 51.03 (4th Ed.).

In the present case, Congress appears to have been more than "influenced" by the DD Act. The legislative history of the Act states:

[T]he Committee chose to utilize the existing Protection and Advocacy Agencies established under the Developmental Disabilities Assistance and Bill of Rights Act as the eligible system. This will require them

to extend their existing services in order to protect and advocate for mentally ill persons.

Sen. Rep. No. 99-109 at p. 7, *reprinted in* 1986 U.S. Code Cong. and Admin. News at 1361, 1367. In fact, the PAIMI Act explicitly cross-references the DD Act in defining the eligible system (42 U.S.C. 10802(2)). Accordingly, the Department has attempted to make both regulations as consistent as possible in places where the language of the Act supports the inclusion of a particular regulatory provision, and where it makes sense programmatically to have similar guidance issued to both parts of the system.

Description of the PAIMI Program

The Act authorizes formula grant allotments to be awarded to P&A systems designated by the Governor in each State to protect the rights of and advocate for individuals with mental illness. The allotments are to be used to pursue administrative, legal, and other appropriate remedies to redress complaints of abuse, neglect, and rights violations and to protect and advocate the rights of individuals with mental illness through activities to ensure the enforcement of the Constitution, and Federal and State statutes.

The P&As have the authority to: (1) protect and advocate the rights for persons with mental illness, and (2) investigate reports of abuse and neglect in facilities that care for or treat individuals with mental illness. P&As may also address issues which arise during transportation to or admission or 90 days after discharge from such facilities. Individuals eligible for services are those who have a significant mental illness or emotional impairment and who live in residential facilities. These facilities, which may be public or private, include hospitals, nursing homes, semi-independent or supervised community facilities, homeless shelters, jails and prisons. P&As have special legal authority to access public and private facilities, residents and clients, and records for the purpose of conducting independent investigations of incidents of abuse and neglect.

Each P&A has a governing authority or board of directors with members who broadly represent and are knowledgeable about the needs of its clients. Also, they each have an Advisory Council to advise the P&A system on policies and priorities to be carried out in protecting and advocating the rights of individuals with mental illness. Sixty percent of the council is comprised of recipients or former recipients of mental health services or families of such persons.

Notice of Proposed Rulemaking

The Department published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on December 14, 1994 (59 FR 64367-64378). Interested persons were given 60 days in which to send written comments regarding the proposed rules. Comments were received from 54 organizations and individuals. Most respondents were from P&A programs; others included individuals, State chapters of the Alliance for the Mentally Ill, and State/county mental health providers. Comments were received from the following national organizations: the National Alliance for the Mentally Ill, the National Association of State Mental Health Program Directors, the Federation of Families for Children's Mental Health, and the National Association of Protection and Advocacy Systems (NAPAS).

All written comments were analyzed and form the basis for changes which the Department has made in this final rule.

Summary of Public Comments and the Department Response

In general, most respondents felt that the proposed regulations provided valuable guidance and would be beneficial in eliminating needless controversy. The majority of respondents want one source of comprehensive guidance applicable to both the PAIMI and the Protection and Advocacy for Persons with Developmental Disabilities (PADD) programs. Most P&A respondents concurred with the comments submitted by NAPAS requesting greater specificity regarding the authority of the P&A systems to gain access to records, to facilities and the residents to conduct full investigations, e.g., to access records as the result of observations during monitoring activities; to conduct investigations and review records of clients routinely subjected to seclusion and restraint; to access jails and prisons; and to expand system access in Federal facilities. P&As and others also sought clarification and conformity regarding the relationship of the Act to other P&A authorizing legislation and relevant Federal statutes. Some respondents had comments only on certain sections or addressed more general concerns such as revisions in eligibility. To the extent possible, the Department has revised the regulations to meet these concerns.

The Department has also made a number of changes in language for clarity and to accommodate adopted recommendations. Where appropriate, the phrases "resident/patient" and

"facility/hospital" have been reduced to "resident" and to "facility"; "patient" and "hospital" are included within the meaning of these terms.

All comments received were carefully considered. The discussion which follows includes a summary of all comments, the Department's responses to those comments, and a description of any changes that have been made in the final rule as a result of the comments. Substantive changes are identified under the appropriate sections, with the exception of some general comments discussed below.

Also, the Department worked with ADD to ensure that as permitted by the Act, the Department's requirements are identical or consistent with ADD requirements that implement the provisions of the DD Act.

Regulations Applicable to Protection and Advocacy for Individuals With Mental Illness

Several commenters suggested it would be useful to incorporate all of the statutory definitions into the regulations arguing that the regulations should provide more than just citations to relevant sections of the Act and that those sections should be restated or paraphrased in nontechnical language. The Department has incorporated much of the relevant statutory language into these regulations. The sections not incorporated were considered not relevant to providing clarification.

NAPAS and others recommended that the regulations be in accord with regulations promulgated under the DD Act to govern the PADD programs. The Department has coordinated development of these regulations with ADD to ensure conformity with their regulations and with the DD Act to the extent possible given the minor differences between the statutes and has appended language from relevant portions of the DD Act, specifically those that clarify the mandated activities of the system.

Two respondents asked that the definition of "individuals with mental illness" be expanded to parallel the broad protections offered by the Americans with Disabilities Act (ADA). The Department responds that the ADA definition is much broader and more complex than the definition provided within the Act; therefore, the Department believes it does not have the authority to expand the definition to this extent through regulation.

One commenter felt that the PAIMI program should expand eligibility for services to include children and youth receiving mental health services in nonresidential, community settings. The

Department is not able, by regulation, to expand the legal mandate of the Act to include any populations, including children in nonresidential settings. However, the Department notes that children with serious emotional disorders are also eligible for services under the PADD program which has a much broader mandate and does include such settings.

Three commenters asked that the regulations contain a list of all P&As (name, address, phone) and spell out their authority. The Department responds that these regulations do spell out the authority of the P&As. A listing of all P&A systems is available from the CMHS Protection and Advocacy for Individuals with Mental Illness Program. The address and phone number of the program are given earlier in the preamble.

One commenter urged CMHS to review any annual evaluations performed on the P&As, particularly taking into account the views of primary consumers and families, and to implement appropriate corrective actions based on the findings. The Department responds that, in addition to reviewing the PAIMI program annual reports, CMHS conducts on-site monitoring and technical assistance reviews. At these visits, CMHS officials solicit commentary, both public and private. To further address concerns or criticisms, the regulations require that each P&A system establish a grievance procedure to assure that individuals with mental illness have full access to services of the system and, for individuals who have received or are receiving mental health services and family members of such individuals, to assure that the eligible system is operating in compliance with the provisions of the Act. (See § 51.25)

One commenter asked that the phrase "mental health" be deleted in all references to the system's advisory council. Inasmuch, as this phrase is not contained in the Act and the deletion of the phrase does not substantively change the regulation, the Department agrees to make this change throughout.

Section 51.1 Scope

One respondent felt that the purpose of the Act should be stated in 51.1. The Department responds that this has already been accomplished under the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections.

Several commenters recommended that this section apply to care or treatment facilities and other persons or authorities with whom the system may be interacting or impacting, and not just to the P&A systems. The Department

responds that these regulations apply to the operation of P&A systems. Although the regulations may have an indirect impact on private and public care or treatment facilities, through State licensing and regulatory authorities, only the P&A systems are subject to the regulations.

Section 51.2 Definitions

Several commenters recommended that the definition of *abuse* be included in the regulation and that it be expanded to include "verbal, nonverbal, mental and emotional harassment and mental or psychological injury." The Department notes that in discussing abuse related to child abuse, the courts and Congress have included verbal, nonverbal, mental and emotional harassment and mental and psychological injury. (See e.g. 18 U.S.C. 3509.) This was done in recognition of the fact that such abuse has as much, and in many cases, even more lasting effect on individuals than physical abuse. The Department can do no less for individuals who are mentally ill, and therefore it is changing the regulation to add the definition of abuse as in the statute and to amend that definition to include "verbal, non-verbal, mental and emotional harassment and psychological harm."

Also, several commenters requested that the term "violation of rights" be added whenever the terms "abuse" and "neglect" are mentioned in the regulation. Some respondents contended that complaints regarding rights violations such as unlawful restraint, inappropriate medications, and denial of communication rights, freedom to practice religion, access to the electoral process, or freedom of association, should be included as specific examples. The Department believes it necessary to clarify the distinction between "abuse" and "neglect" and "violation of rights" because the statute draws a distinction between them granting to the systems the power to investigate "abuse" and "neglect" and to protect and advocate on behalf of the rights of individuals with mental illness. The Department believes that when an individual's rights as defined in the Bill of Rights for Persons with Mental Illness established by the President's Commission on Mental Health (Title II of the Act) are repeatedly and/or egregiously violated, this constitutes abuse. While the Bill of Rights provides useful guidance, it should not be considered full or limiting as to types of rights violations. It is not necessarily true, however, that every violation of a person's rights is in and of itself "abuse" as defined in the Act.

The Department declines the opportunity, however, of defining the threshold at which a violation of an individual's rights constitutes abuse, leaving that decision to the systems which will have intimate knowledge of the situation based on its monitoring of facilities and its discussion with individuals with mental illness.

A large number of commenters felt that the definition of "Care and Treatment" should be broadened. They argued that the definition is too narrow to include all facilities providing 24-hour care, and that the current definition is more oriented to "treatment" than to care. Most asked to eliminate the term "overnight care" because it is too restrictive. The Department believes that the requirement that the facility provided overnight care meets the intent of the Act which is to restrict its eligibility to persons who are/were residents of facilities or who are/were within 90 days of discharge from such facilities. Overnight care serves only as a minimum requirement; covered facilities may provide up to 24-hour care.

Many others argued that the definition of *care* should include elements of traditional support services such as case management; accompanying patients to outpatient centers; medical appointments or day treatment centers; vocational training services; transportation; education programs; employment programs; and provision of food, water and clothing. The Department responds that, to the extent that any of the above-suggested inclusions are provided to individuals with mental illness in eligible care or treatment facilities, they should be considered as incorporated within the meaning of "services to prevent, identify, reduce or stabilize mental illness or emotional impairment," which is used by the National Institute of Mental Health and the CMHS based on the survey format *Mental Health Service System Reports*, "Data Standards For Mental Health Decision Support Systems," which was developed through consensus in the mental health field.

Several commenters suggested that the definition of "Complaint" should include both written and informal oral communications such as telephone calls (including anonymous calls) that, in the judgment of the system, state credible allegations of abuse, neglect or other violation of rights. Further, the *Alabama Disabilities Advocacy Program v. J.S. Tarwater Development Center*, 894 F. Supp 424 (M.D. Ala. 1995) ruled that an anonymous telephone message alleging

abuse at a facility constituted a valid "complaint" justifying access to records under the records access provisions of the Act. The court found that to require the complainants to divulge their names or reduce allegations to writing and sworn testimony or make charges of a particular nature would dilute the Act and too narrowly construe the complaint requirement. The Department has included written and oral communications in the definition. Also, the word "report" was added to have the same meaning as complaint. A complaint or report may be received from any source or individual.

The Act states that a P&A system has the authority to investigate incidents of abuse and neglect that are either reported to the system or where there is probable cause to believe that the incidents have taken place. The Department believes that media accounts and newspaper articles can be viewed as the equivalent of a complaint when they provide details about a specific incident of abuse or neglect. While such reports are not specifically directed at the P&A system, they are published with the expectation that public officials responsible for conditions will act to stop abuse. P&A systems have that role. This does not preclude a P&A system from acting on behalf of a unnamed client or on behalf of a class of people. (See § 51.6(f).)

A definition of *Designated Official* has been added for clarity, to conform with ADD regulatory definitions. This individual is accountable for the proper use of funds and conduct of the P&A system.

Many commenters asked that a definition of *Facility* be included and that it specifically include all types of community living arrangements. The Department agrees that a definition of "Facility" should be added, but does not agree that the definition include all types of community living arrangements. The intent of the Act was to focus only upon facilities that provide "care or treatment," i.e., those facilities that provide overnight care accompanied by services to prevent, identify, reduce or stabilize mental illness or emotional impairment, including supportive services, even if only "as needed" or, under a contractual arrangement, up to 24-hour care.

The Department has added a definition of "Full Investigation" to clarify what an investigation entails and to conform to the PADD regulation. We note that while an investigation involves access to facilities, PAIMI systems have authority in their monitoring role to access facilities

regardless of whether or not a complaint has been registered or probable cause exists.

Several commenters asked that the definition of "Individual with Mental Illness" be included. The Department agrees that the definition would add clarity to the regulations on a substantive issue. It has added the definition provided in the Act, clarified as addressed below regarding jails, prisons and detention facilities.

Commenters requested that the regulations clarify whether P&As may serve prisoners with mental illness who are maintained within the general prison or jail population (not just the mental health units of such facilities) and who may receive mental health services from time to time. The Department concurs that a system may assist prisoners or detainees with mental illness who are maintained within the general prison or jail population and who may receive mental health services from time to time as well as those who are maintained in special mental health units. This language has been incorporated into the definition of "Individual with Mental Illness."

The Department would like to clarify some confusion in the statute with regard to jails and prisons. In section 102(3) of the Act jails and prisons are clearly listed as facilities. Yet section 102(4) in the definition of "individual with mental illness," indicates that such a person includes an individual who has a mental illness and "who is involuntarily confined in a municipal detention facility for reasons other than serving a sentence resulting from a conviction for a criminal offense." Is the statute suggesting that if a person with a mental illness is convicted of a criminal offense and sentenced to a State or Federal jail or prison that provides care or treatment, that person is covered by the Act, but one confined to a municipal detention center that provides care or treatment is not covered? To clarify this ambiguity, the Department is expanding the definition of "individuals with mental illness" to include persons in a detention facility, jail or prison which provides overnight care or treatment, whether they have been convicted of a criminal offense or not, and whether the facility is municipal, State or Federal.

Others requested guidance on which, if any, juvenile detention facilities are included and whether juveniles with a mental illness who are serving sentences for conviction for a crime, are excluded if they are housed in a juvenile "detention facility." The Department responds that juveniles with a mental illness who are in an

overnight municipal detention facility, jail or prison which provides care or treatment are covered whether they have been convicted of a criminal offense or not.

Several respondents addressed the definition of "Legal Guardian, Conservator and Legal Representative." One suggested that the phrase "or agency empowered under State law to appoint and review such officers" was confusing and should be eliminated. Others asked that, to avoid conflicts of interest, a legal guardian should not include a family member with whom the mentally ill person resides who is also the payee and responsible for conducting the business of the person. The Department responds that it does not intend to supersede State laws regarding which agency may appoint and review guardianships nor will it mandate for States whom they shall name as guardian.

Some felt that the restriction on officials responsible for the provision of health and mental health services in the definition of *Legal Guardian* did not go far enough because those same officials often have authority to appoint others as conservators. The Department agrees in this instance, and will change the definition to include the phrase "or their designees." The Department reiterates that a legal guardian for the purposes of this regulation is an individual who is appointed by the appropriate State powers to be a legal guardian for the individual and who has the authority to consent to health/mental health care or treatment for the individual with mental illness.

Other comments were in support of not including: guardians *ad litem* appointed for limited and specific purposes other than health/mental health care and treatment; representative payees; persons appointed during probate proceedings as administrator or executor of the estate; and lawyers representing persons in divorce proceedings, tax hearings or in criminal matters unrelated to mental health status. The Department agrees that all of the above are restricted within the current definition.

One respondent asked whether the definition included parents of minor children. The Department responds that natural or adoptive parents are legal guardians unless the State has appointed another legal guardian under applicable State law.

Several commenters suggested that inappropriate confinement or placement in a facility should be included under "Neglect." The Department understands the comment to be about confinement, and it believes that treatment should be

based on principles of accepted practices of quality mental health care. If a person with a mental illness is confined or placed in a facility with disregard to the principles of accepted practice, such confinement could be abuse or neglect.

One respondent called for certain rights of consumers to be included such as the provision of palatable food, adequate bathroom breaks, access to medication, allowance for arrangements to be made for ongoing care of pets, etc. The Department responds that the Act does not define "rights" but rather provides in Title II, a Bill of Rights ("Restatement of Bill of Rights for Mental Health Patients") and recommends that States, in establishing laws that protect and serve individuals with mental illness, take into account these recommendations.

A large number of commenters requested that a discussion of probable cause be moved to the definition section. The Department agrees and has done so. Others suggested that the phrase "or may be" should be inserted in the probable cause definition to amplify "has been subject to abuse or neglect" stating that this would be consistent with Congressional intent that the P&A systems ensure the protection of individuals with mental illness. The Department agrees and has included the phrase "or may be at significant risk of being subject to abuse or neglect" in the new definition.

In addition, a large number of commenters supported the proposal that *probable cause* be defined as a belief based solely on the independent judgment of the system (advocate, attorney, or other person authorized to act on behalf of the system). Commenters argued further that it be made clear that the system is not required to disclose the basis of its probable cause finding to a facility or to any other third party; their determination should not be subject to review by a facility, authority, or Court or some other third party. The Department agrees that the determination of whether sufficient probable cause exists shall be based on the independent judgment of the P&A system (that is, the judgment of the advocate, attorney, or other person authorized to act on behalf of the P&A system); however, it is outside of the Department's purview to give sole discretion to the P&A system in this matter. The Department does not have the authority, by regulation, to insulate a P&A system from having to articulate the basis of its probable cause determination when requested.

In several places, the statute balances the need to maintain the confidentiality of individual records with the need to protect an individual from abuse and neglect. In general, the statute requires consent before any records are released to the P&A. However, in certain circumstances where the individual does not have a guardian, or where the guardian is unavailable or refuses to act, the P&A may obtain records without consent of the responsible party, if there is probable cause to believe that the individual has been or may be subject to abuse and neglect. In these situations, the facilities may be required to violate State law in order to provide the P&A with the records to which the statute and these regulations give them access. In the Department's view this is a very serious matter that requires a careful balancing of all of the interests represented here. Certainly, therefore, it is reasonable to expect that the system may be required to demonstrate that there was an adequate basis to justify the release of confidential records without consent.

However, the Department understands the difficulty the P&A systems confront in these situations. The P&A systems often receive complaints from individuals who fear reprisal if they come forward. If the P&A systems are required to disclose the names or other identifying information of those individuals who contacted the P&A with complaints about abuse and neglect, it is likely that far fewer people will come forward. This will severely impair the ability of the P&A systems to carry out statutorily mandated functions. Accordingly, the Department has added language to the regulation in section 51.45(a)(1)(iii) which makes clear that the P&A system must keep confidential information regarding individuals who report incidents of abuse or neglect, or who furnish information that forms the basis for a determination of probable cause.

One commenter believed that "reasonable suspicion" should be used instead of "probable cause" arguing that it would provide a lower threshold for inquiry. The term "probable cause" is used in the Act.

A comment was made that the definition of "System" should be clarified so that when the regulations say "the system shall have the authority and access to * * *" it is readily understood as meaning all authorized employees of that system. This suggestion was countered by a number of State mental health facility operators who said that only attorneys should have access to patients and not other PAIMI program advocates. The

Department responds that the Act grants access to the PAIMI program. Thus anyone acting on behalf of the system is to be granted access to all areas of the facility which are used by residents or accessible to residents.

Subpart A—Basic Requirements

Section 51.3 Formula for Determining Allotments

One commenter recommended that the formula for determining the amount of allotments be revised. The Department responds that it cannot change the current language of the law by regulation.

Section 51.5 Eligibility for Allotments

A commenter under NPRM section 51.27 felt that the system should be obligated to budget for training. The Department agrees that the system should budget for training, but does not wish to regulate this matter. The Department does require an annual report that includes a PAIMI budget.

One respondent asked for clarification regarding who is required to submit the assurances. The commenter noted that the system is authorized to provide the assurances directly to CMHS but that the "supplement and not supplant" assurance be signed by the Governor before being submitted by the system. It was recommended that paragraph (d) be deleted, and that the nonsupplanting assurance be included with the assurances described in paragraph (c). Another commenter suggested that there be one set of assurances for an entire P&A system, rather than viewing PAIMI as an independent program which is simply housed with PADD programs. The Department wishes to clarify that the system shall submit and sign *all* assurances *but* the "supplement and not supplant" assurance must bear a gubernatorial signature. This assurance may be a copy of an earlier similar assurance submitted to ADD as long as it can reasonably be construed as covering the PAIMI program as well. Any future "supplement and not supplant" assurances shall explicitly refer to the PAIMI program.

Section 51.6 Use of allotments

Almost half of the commenters urged that the regulations clarify whether or not a P&A system has standing to take legal action in its own name. It was explained that mechanisms to protect individual confidentiality are not foolproof, and that facility residents too often fear retaliation from their care providers as a result of their participation in a lawsuit concerning institutional conditions or other matters.

Another reason for enabling P&A systems to have independent standing is that, unfortunately, the credibility of an individual with a diagnosis of mental illness is all too often automatically questioned. In addition, it is reported that very often persons with mental illness who wish to play a direct role in a lawsuit are unable to do so because their legally authorized representative refuses to consent. These respondents claim that it is extremely time consuming and costly to have to litigate the question of standing before being able to proceed to the merits of a case. They maintain that potential defendants might settle matters more quickly, prior to the initiation of legal action, if they knew that the P&A system itself might bring the suit and not the resident.

The Department agrees in part and disagrees in part. The concept of "standing" derives from Article III of the Constitution. Article III limits the "judicial power" of the United States to the resolution of "cases" and "controversies." In various cases addressing the issue of standing, the Supreme Court has held that "at an irreducible minimum. Article III requires the party who invokes the court's authority to 'show that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant,' and the injury 'fairly can be traced to the challenged action' and 'is likely to be redressed by a favorable decision.'" See *Valley Forge Christian College v. Americans United for Separation of Church and State*, 454 U.S. 464 (1982). Thus, the issue of standing is a basic jurisdictional issue that has been left to the judiciary to determine based on the facts and circumstances of a particular case.

In promulgating regulations, the Secretary must act within the bounds of her authority and develop rules that are consistent with the language of the statute. The Act does not contain any provision that would provide the Secretary with sufficient authority to, by regulation, grant a right of standing that is not explicitly noted in the statute. The Department, however, points out that the legislative history of the 1994 DD Act Amendments (Sen. Rep. No. 103-120, 103rd Cong., 2d sess., 39-40, reprinted in 1994 U.S. Code Cong. and Admins. News at 164, 202-203), strongly supports the view that, without showing injury to itself, a P&A system does have standing to bring suit on behalf of persons with disabilities. Although Congress declined to amend the DD Act to insert a right of standing, the report stated that "the current statute is clear that P&A systems have

standing to pursue legal remedies to ensure the protection of and advocacy for the rights of individuals with developmental disabilities within the state.”

Further, the following courts have affirmed the P&A systems independent standing: *Alabama Disabilities Advocacy Program v. J.S. Tarwater Development Center*, No. 95-T-385-N (M.D. Ala. July 6, 1996); *Rubenstein v. Benedictine Hospital*, 790 F. Supp. 396 (N.D. N.Y. 1992); *Goldstien v. Coughlin*, 83 F.R.D 613 (W.D.N.Y. 1979); *Hershberger v. Missouri Protection and Advocacy Services, Inc.*, No. 48169 (MO Ct. of Appeals, August 2, 1994).

In light of the report language and the case law cited above, while the Department cannot offer standing in regulations, it can and does permit systems to use funds for the costs incurred in bringing lawsuits in its own right and has added this provision at 51.6(f).

Section 51.7 Eligibility for Protection and Advocacy Services

Several commenters requested that the definition of “Individual with Mental Illness” should be included in this section as well as in the definition section. The Department has incorporated the definition in the Definition section of this regulation (section 51.2) and feels that this is sufficient.

Section 51.7(a)(2)

Department staff recommended that all of the requirements for eligibility for P&A services be incorporated into the regulations. Paragraph (2) regarding the 90-day post discharge requirement as stated in section 105(a) of the Act has been added to address eligibility requirements.

It was requested that the regulations clarify whether PAIMI programs may address any rights violations that occur within 90-days of discharge from a facility, or whether such violations must be related to the care of treatment provided by the discharging facility. The Department responds that the Act itself does not restrict the nature of advocacy services which may be provided during the 90-day post-discharge period, but the legislative history shows that the general intent of Congress was that the 90-day post-discharge period was primarily to enable redress against facilities which discharge persons without providing appropriate community follow-up and housing services.

Several commenters supported the section of the regulation that allows P&A systems to address issues which

occurred within the 90-day post-discharge period, even though they may be brought to their attention after expiration of the 90-day period. The Department agrees that neither the Act nor the final regulations place a time limitation on the authority of the P&A system to address complaints of abuse or neglect that occurred during the 90-day post-discharge period.

Section 51.7(a)(3)

One commenter recommended that this section be modified to enable requests for representation in Federal and other facilities by a family member, friend or other concerned party acting on behalf of an individual with mental illness who, by reason of incapacity or otherwise, is unable to request services him/herself. It was further recommended that P&As be obligated to initiate a preliminary investigation upon receipt of a complaint from a family member. While the Department agrees that family members and, in fact, anyone, should be able to initiate a complaint or report to the PAIMI program, the intent of this regulation is to meet the special limitations of P&A authority in Federal facilities and to distinguish between persons who may make a report and those who are legally authorized to actually request or consent to representation by the P&A. Only the individual with mental illness, or, for individuals lacking capacity to consent, a legally authorized representative—as defined in the regulation—can request or consent to representation by the P&A.

Section 51.7(b)

One commenter asked that the word “procedures” in this section be changed to read “acts or omissions” which have subjected the individual to abuse or neglect or otherwise violated his/her rights. It was argued that in one State there are literally hundreds of individuals who are under civil commitment orders and being held in State facilities solely by reason of the failure of the public mental health system to provide them with adequate discharge planning. The commenter found that the most effective strategy is to challenge the civil commitment order and/or to file a petition for discharge through the probate court. The regulation would suggest that the system only has authority to undertake these actions when there is a procedural, as opposed to a substantive, violation. The Department agrees and will change the wording of the regulation as suggested.

Section 51.8 Annual Reports

Subparagraphs (2), (3) and (4) of section 51.8 of the NPRM were removed to enable the Department more flexibility regarding report requirements. The Annual Reports will be implemented under the legislative authority pursuant to section 105(a)(7) of the Act (U.S.C. 10805(a)(7), not regulatory.

Section 51.9 Financial Reports

This section was deleted because the Financial Status Report requirement is included under section 51.4 Grants Administration Requirements, 45 CFR Part 74—Administration of Grants.

Section 51.10 Remedial Actions

In response to Department staff concerns about the lack of clear requirements about review and monitoring activities of grantees, additional language was added to strengthen requirements regarding Department requests for information and documentation, corrective action plans and ongoing implementation status reports.

Subpart B—Program Administration and Priorities

Section 51.21 Contracts for Program Operations

Section 51.21(b)

A few respondents recommended that organizations with which the PAIMI program contracts should be only those with proven knowledge about mental illness and the service system. The Department agrees that PAIMI program contractors, in their capacity to perform protection and advocacy activities, should demonstrate experience in working with individuals with mental illness and has added this language to the regulation.

Section 51.21(b)(3)(viii)

To conform with requirements which have been added at 51.27(c) that P&As provide training for staff to conduct “full investigations,” a similar provision has been inserted here to ensure that PAIMI service provider contractors must also provide such training.

Section 51.22 Governing Authority

Section 51.22(a)

Department staff suggested that the requirement in the Act regarding the establishment of program priorities and policies jointly with the advisory council be inserted here to strengthen the provision. It has been added.

Sections 51.22(b) (1) and (2)

The Department notes that the Act currently requires only that the governing board be composed of members "who broadly represent or are knowledgeable about the needs of the individuals served by the system" whereas the DD Act states that the board "shall include individuals with developmental disabilities who are eligible for services, or have received or are receiving services, or family members, guardians, advocates, or authorized representatives of such individuals." The Act requires that only *one* individual on the governing board, specifically the Chair of the PAIMI Advisory Council, be an individual who has received or is receiving mental health services or a family member of such an individual.

Several respondents suggested that this regulation should be revised to read: "an individual or family member who serves on a system's governing board in a representative capacity must have direct experience with the needs of clients served by the system." Another commenter recommended that at least 25 percent of the governing board's membership should be composed of persons nominated by consumer and family member organizations, who have demonstrated sustained leadership and commitment to achieving improvements in the system of care, that "no individual may serve more than four successive years as a member of the governing authority," and that terms should be staggered. A small number of commenters wanted to add a requirement for the governing board to annually evaluate the performance of the P&A system director and the PAIMI director adding that as part of their evaluation, comments on performance and leadership from consumer and family member organizations within the State shall be solicited and the results of such evaluation be used as a basis for the establishment of any subsequent year's performance standards. The Department responds that it considers each of these suggestions as reasonable and good practice but does not wish to enforce *all* such specific policies through regulation.

The Department has sufficient evidence concerning governing board memberships to support the need to enhance the composition of P&A governing boards to balance the current inequitable representation of PAIMI client constituencies. Therefore, the Department is *proposing* to add language to the regulations requiring that the membership of the governing board shall include at least a 25 percent

representation of individuals with mental illness and of family members of individuals with mental illness. *The Department solicits further comment on this issue.* Depending on the comments received, the Department may revise the section. To ensure consideration, comments must be submitted to the address given earlier in the preamble within 60 days after publication of this final rule.

The Department agrees with the need for rotational and limited number of board member terms and for board evaluation of the P&A system director; therefore, it has added such language. The term of office of a board member shall be for 4 years and the member may not be reappointed to the board for a 2-year period. Rotational and a limited number of terms of board members encourage recruitment of persons bringing new skills and ideas to the board, prevent bias and burnout, and permit more consumers to participate in governing the system. Annual evaluation of the P&A director by the board fosters performance accountability.

Section 105(c) of the Act states that the governing authority shall "be responsible for the planning, design, implementation, and functioning of the system." The Department does encourage the P&A systems to develop operating policies that incorporate requirements that further encourage board membership policies to identify relevant criteria for member selection and qualifications, and for an annual review of the Executive Director's performance that takes into account the appraisals of relevant constituency groups.

*Section 51.23 Advisory Council**Section 51.23(a)*

The Department recommended that the authority and responsibility of the Advisory Councils be strengthened to ensure the ability to provide advice and recommendations to the P&A without being unduly influenced by the P&A. This independent critical eye from individuals served by the P&A can only improve its services. The Department inserted language requiring that the council provide "independent" advice on program policies and priorities.

Section 51.23(b)

One commenter suggested that individuals who have received or are receiving mental health services should appear first in the listing of the council's composition. The Department responds that for purposes of clarity the language should be consistent with the Act.

Several commenters wished to add a requirement in this section that advisory council members who are "individuals from the public who are knowledgeable about mental illness" must "have demonstrated a substantial commitment to improving mental health services" as a conditions of their membership. The Department agrees that such criteria is useful and inserted the language after "mental illness" in this section.

Section 51.23(b)(1)

A small number of commenters were concerned that, to ensure expertise about how the system is presently serving children and youth, at least one family member on the council should be the primary care giver for an individual who is currently a minor child or youth who is receiving or has received mental health services. To ensure the inclusion of knowledge and experience regarding children with serious emotional disturbances and the mental health services they need, such language was added to this section.

Section 51.23(b)(3)

Department staff recommended that an annual minimum number of advisory council meetings be required in order to allow the council sufficient time to conduct its business and provide advice on program policies and priorities. The Department has added language requiring that councils meet, at a minimum, no less than three times a year. This in no way should be considered limiting.

In response to the recommendation that governing board members be limited in the number of terms they serve, the Department believes this would also be useful for the advisory council. Rotational and a limited number of terms of council members would encourage recruitment of persons bringing new skills and ideas to the council, prevent bias and burnout, and permit more consumers to participate in advising the P&A. The Department agrees with the need for rotational and limited number of board member terms and for board evaluation of the P&A system director; therefore, it has added such language. The term of office of a board member shall be for 4 years and the member may not be reappointed to the board for a 2-year period.

Section 51.23(c)

There was a recommendation to require that status information and analysis be provided to advisory council members to address each of the following:

(1) Individual advocacy services, including case selection criteria, the

availability of monetary resources, and special problems and cultural barriers faced by individuals with mental illness who are multiply handicapped or who are members of racial or ethnic minorities in obtaining protection of their rights;

(2) Systemic factors, including

(a) the adequacy and coordination of information sharing with like organizations within the State and nationally; and

(b) the adequacy of State psychiatric consumer services, rights laws and their enforcement with regard to:

(i) managed care, HMOs, and similar community organization protections, and

(ii) State institutions or State-operated facilities.

The Department does not wish to require numerous specific items to be provided which impose additional burdens and are not contained in the Act. However, the Department believes that the P&A system should provide as much information as necessary to enable the council to perform their responsibilities efficiently and responsibly. If information such as identified above is readily available, then it should be provided. Also, nothing should prohibit council members who desire such detailed information from seeking it from the system or from national technical assistance resources. In line with the Department's initiative to implement program performance outcome measures, language has been added under 51.23(c) to require that program performance outcome evaluation results be provided to the advisory council.

Section 51.23(d)

It was recommended that reimbursement for the cost of day care for dependents of individuals with mental illness be extended to include minor children and youth without disabilities. The Department disagrees; the costs of day care can be reimbursed only for persons with children who have a serious emotional disturbance, because this enables participation by family members of such individuals in keeping with the intent of the Act. The term "child care" was added and the description for equivalent expenses was expanded to further clarify the requirement.

Section 51.24 Program Priorities

Section 51.24(a)

A modification was recommended whereby the advisory council would approve the PAIMI priorities and policies before being submitted to the

governing authority for approval. The Department believes that section 105(c)(2) of the Act is very clear in saying that the governing authority is solely responsible for planning, design, implementation, and functioning of the system. It is also very clear that annual priorities of the system are to be developed jointly with the advisory council.

The Department believes that to ensure consideration of systemic and legislative needs and issues, P&A systems should include priorities for systemic and legislative activities in developing annual priorities and has added this requirement.

Section 51.24(b)

Another commenter asked that the requirement be expanded so that public commentary on a system's annual priorities include comments regarding the general operations of a P&A system. The Department responds that the requirement to obtain public commentary already includes commentary on general operations, i.e., activities of the P&A system, as a part of establishing the system's annual priorities.

Section 51.25 Grievance procedure

The Department modified this section to address the confusion in the use of two terms—"grievances" and "complaints." To conform with the Act, only the term "grievance" has been used.

Section 51.25(a)(2)

One commenter noted that the second class of complaint, which is to "assure that the eligible P&A system is operating in compliance with the Act" is confusing and needs clarification. The Department responds that this section requires the P&A system to address grievances about how it is operating and to ensure that its activities and policies meet the intent of the Act. Failure to conduct activities in accordance with the requirements of the law is a serious breach of public trust and this is a different issue than ensuring that clients or prospective clients have access to the services provided by the system.

A second commenter expressed reservations about the license provided by this regulation to stimulate "generic" grievances against a P&A system based on unfounded assertions that the P&A is not in compliance. The Department responds that inasmuch as P&As are funded with public monies, they must adhere to the statutory mandate and provide access to their constituencies and respond to questions or complaints concerning their activities. The

Department believes that a P&A which is operating in accordance with these regulations will have no difficulty responding to generic grievances with respect to compliance with the Act.

Section 51.25(b)(1)

One respondent did not support a "final review" of grievances by the governing board. The Department strongly believes that the governing board should have final responsibility for resolving contentious grievances. Department staff recommended that language be added to require that in cases where the governing authority is the director of the P&A, a final review be done by a separate entity. It was explained that in State P&A agencies where the governing authority is a single person and may be the person to whom a grievance is directed, it is not appropriate for that person to review and make a final determination on the grievance. The Department agrees and has added language requiring that P&As provide for final review on appeal of grievance decisions to an independent board or a superior in cases when the governing authority is a single person.

Section 51.25(b)(2)

One respondent argued that since advisory councils do not have authority concerning policy and personnel issues, complaints received should be made to the governing authority, which is involved in policy and personnel issues. The Department wants to clarify that advisory councils are not involved in the grievance process. This requirement merely states that the system should report annually to the council summarizing the general nature of the complaints or grievances against the PAIMI program. The Department believes that such information is extremely relevant in developing the following year's priorities and objectives. However, no identifying information concerning clients or staff and no personal identifiers concerning the grievants should be included in any such reports.

One commenter asked that this requirement include: "a trend analysis of the sources, issues, timeframes and other pertinent factors relating to grievances received." The Department does not wish to develop specific format and content requirements for these reports; the governing authority and Advisory Council should identify this for themselves.

Section 51.25(b)(4)

Responsive to concerns by Department staff that prospective clients, clients or persons denied

representation receive prompt notification about the grievance policy and the progress being made on their grievance, the Department has added a requirement that the P&A system establish as part of its grievance procedures timetables to ensure prompt notification.

Section 51.26 Conflicts of Interest

A small number of commenters suggested rewording the section as follows: "further, conflicts of interest should consider the extent to which an individual's personal or political allegiances may inhibit, or appear to inhibit, the performance of a position or its attendant duties in the best interests of persons with a mental illness." While the Department appreciates the general concern being raised, it would not be useful for a Federal regulation to address such a consideration. The P&A systems may develop personnel policies which consider the extent to which an individual's experience contributes to the promotion and advocacy of individual rights.

Section 51.27 Training

One commenter suggested that training should be limited to topics consistent with carrying out activities under the Act. The Department agrees and believes that the language of the regulation as stated sufficiently communities this. However, responsive to demonstrated need and repeated requests from P&A system staffers, and in conformity with ADD, the Department has included under (c) a specific type of training thought to be essential to the effective implementation of P&A system activities, namely training to conduct full investigations.

Another respondent felt that the system should be obligated to budget and provide support for training as necessary to meet the established priorities. The Department responds that the system is required to have a staff "which is trained or being trained" and sets aside "not more than 10 percent of its allotment to spend on technical assistance and training." The Department believes that training for staff is obligatory but that, for the most part, the nature of such training should be determined by the system to meet individual staff needs and any special foci of its annual goals and objectives. Additionally, the Department has added language at 51.23(c) requiring that the advisory council be provided fiscal data on the amount expended and projected for training of each the advisory council, governing board and staff.

Several respondents asked that the regulations require that families and

consumers be involved in training and that such individuals also be involved in the planning and implementation of training for PAIMI advocates. The Department responds that the use of individuals with mental illness or family members of such individuals can be extremely valuable resources for PAIMI training but does not wish to require this by regulation.

One commenter felt that training on working with families should be extended to all support personnel working in the system. The Department will not require this but urges P&A systems to provide all necessary training to individual staff based upon an ongoing assessment of their needs.

Counter opinions felt that mandating specific kinds of training creates an intolerable situation for P&A systems with minimal resources and suggested that the language in paragraphs (a) and (b) be eliminated. The Department responds that this specific training is mandated by the Act and believes that there is justifiable cause for requiring it. The Department believes that every system employee should be provided with such training and that it is appropriate to require specialized training or "refresher" training as necessary.

Sections 51.28-51.30 Reserved

Subpart C—Protection and Advocacy Services

Section 51.31 Conduct of Protection and Advocacy Activities

Section 51.31(a)

A few commenters recommended that language on use of appropriate techniques and remedies, which originally appeared in section 51.32(a), would be more appropriate as an introduction to this section. The Department agrees and, in conformity with ADD regulatory structure, has moved this language to 51.31(a). Also, in response to commenters' suggestions in the definition section that the term "violation of rights" be added whenever "abuse" and "neglect" are used, the Department added language in this section indicating that appropriate remedies may be used to address abuse, neglect, or violation of rights.

Section 51.31(b)

Several commenters believed that the regulations did not directly address the potential for redundancy with other statewide advocacy programs and felt that the PAIMI program should be required to coordinate and collaborate with any established, State-funded agency providing patient rights

advocacy services. P&A system efforts should augment current services and not duplicate them. The Department notes that in having an assurance that forbids the State from using Federal funds to supplant the level of non-Federal funds, it effectively requires augmentation. (See section 51.5(d).) Also, the Department notes that the requirement for annual priority setting necessitates coordination with other advocacy groups and is accomplished, in part, by requesting and responding to public commentary. The Secretary further requires that annual reports of the PAIMI program identify other groups with whom it worked cooperatively on activities. Ongoing coordination and collaboration is absolutely encouraged by the Department.

To conform with ADD regulations, the Department has added a requirement that no policy or practice shall be implemented by the P&A system that restricts the remedies which may be sought on behalf of individuals with mental illness. This is to ensure that a P&A system use all the remedies, e.g., administrative and legal, it has available to redress complaints brought by clients.

Section 51.31(c)

Many commenters strongly supported the requirement that the PAIMI program establish an "ongoing presence" in residential mental health care facilities, but one respondent wanted it made clear that facilities have no obligation to provide office space, telephones, or other financial support to the system. The Department responds that the regulatory language does not imply any such obligations. The Department encourages the regular appearance and presence in facilities by PAIMI advocates but does not necessarily intend that on-site offices be maintained. However it is expected that facilities will provide space for unaccompanied private conversations with residents and clients.

Section 51.31(d)(1)

One commenter suggested that this section establish consistent policies regarding access to day rooms, living quarters, and treatment areas. The Department responds that this section includes interactions with residents or staff in all areas of facilities used by or accessible to residents. To ensure this, the Department will insert the phrase "all areas of the facility which are used by residents or are accessible to residents" in sections 51.42(b) and (c).

Section 51.31(e)

Department staff recommended that section 51.27(b) regarding training for individuals who are not program staff, contractors, board or council members be moved to section 51.31 because its content is more appropriate under the conduct of P&A activities. This has been done. A respondent felt that training in self-and peer-advocacy skills should be provided by the P&A system. Self-advocacy training involves teaching the mental health consumer skills, and providing support and assistance to present his or her views either about personal treatment or about the wider service needs, and peer-advocacy training involves providing mental health consumers with skills to support and assist other mental health consumers about personal treatment or about wider service needs. The Department agrees that such training is immensely valuable and may be provided but does not wish to mandate it.

Section 51.31(f)

One respondent noted that this regulation appears to authorize systemic advocacy and argued that P&A system activities should be limited exclusively to matters of abuse, neglect and rights violations. The Department does not agree. P&A systems are clearly authorized by section 101(b)(2)(A) of the Act to engage in systemic, and other types of advocacy activities, including the pursuit of administrative, legal and other appropriate remedies to ensure that the rights of individuals with mental illness are protected. One commenter believed "that not enough attention is being paid by the P&A systems to Advocacy," that persons with mental illness need advocates who can plead for their just causes in public forums and before legislative executive bodies and government agencies, and that a separate section should be added to the regulation to address the advocacy role. The Department agrees that P&A systems shall carry out systemic advocacy—those efforts to implement changes in policies and practices of systems that impact persons with mental illness, and legislative activities—those involving monitoring, evaluating, and commenting upon the development and implementation of Federal, State, and local laws, regulations, plans, budgets, taxes and other actions which affect persons with mental illness. Legislative activities was addressed under section 51.6(b) of the NPRM, but has been moved here because the Department believes that system activities related to monitoring,

evaluating and commenting on the development and implementation of Federal, State and local laws, etc., fit more appropriately under this section on conduct of P&A activities. The Department has also added language at paragraph (f) requiring P&A systems to address systemic activities.

Section 51.31(g)

A number of respondents asked that the regulations clarify that a probable cause determination of a PAIMI program may be based on information obtained from "monitoring or other activities" and that this be understood to apply to a wide range of similar activities. The Department agrees and has added language about "monitoring and other activities" and "general conditions affecting health or safety" under this paragraph.

Section 51.31(h)

This section was added to ensure equal applicability to PAIMI programs and to conform with identical provisions which appear in the DD Act and ADD regulations. This requirement assures that a State P&A system will not be hindered by State personnel or administrative policies in carrying out advocacy activities.

Section 51.31(i)

Two commenters asked that there be a provision stating that State laws which grant P&A systems greater access are not superseded by the Act. The Department agrees that where State laws give the system greater authority than these regulations, such laws shall prevail and has inserted subsection (i) to ensure equal applicability to PAIMI programs in conformity with provisions appearing in the DD and ADD regulations. Also, the Department has inserted language to make clear that State law must not diminish the authority of the Act.

*Section 51.32 Resolving Disputes**Section 51.32(a)*

For clarity, the first half of the NPRM language for this section has been moved to 51.31(a) The remainder of the original is in this section.

Section 51.32(b)

One commenter argued that the phrase "disputes regarding a particular course of treatment" should not be singled out from other disputes regarding a person's rights, particularly because, under both Federal and State law, there is an explicit right to refuse treatment under certain circumstances. The Department agrees that it does not appear useful to specify a particular

type of dispute and will delete the phrase.

Another commenter noted that this provision might be used by hospitals and clinicians to require P&A systems to demonstrate that negotiation and mediation had been initiated and had proven unsuccessful before a legal action or even a formal administrative complaint could be initiated. The Department notes that under paragraph (d) the system has the authority to take action when it believes the administrative process is not resolving an issue within a reasonable period of time, and further that when the situation is an emergency, the system can bypass the administrative process. Further, paragraph (e) states that the Act "imposes no additional burden respecting exhaustion of remedies" and that the intent of this section is only that nonadversarial techniques be used for resolution "whenever possible."

Another respondent feared that the requirement to involve family members might discourage or prohibit eligible individuals from participating in a legal action. The Department responds that this section deals only with nonadversarial processes. The Department notes that under this subsection family members have the opportunity to participate in negotiations; however, individuals who are not under guardianship are legally competent to decline to have family members involved.

Section 51.32(c) (d) and (e)

A number of commenters disagreed with the provision that a PAIMI program should be required to "exhaust all administrative remedies" prior to initiating a legal action; only one respondent encouraged this interpretation. One commenter suggested that this requirement had been used by the Office of Attorney General as a tactic to delay action on cases: "It is the client who cannot get services and whose health continues to deteriorate who suffers from this process." A large number of commenters recommended that the word "all" be deleted, arguing that exhaustion should be required only in circumstances where a clear administrative scheme exists. Others felt that the section should adopt the general principles of administrative law which relieve a party of the need to "exhaust" when such action would be ineffective or futile. It was further argued that this regulation could be construed to impose a higher burden on P&A systems to use administrative remedies and that the last sentence under (a) adequately addresses this

issue by encouraging P&A systems to use negotiation, conciliation, or mediation early in the protection and advocacy process.

The Department notes that the language which appeared in the NPRM is more restrictive than intended by the Act; the phrase "in a Federal or State court" was inadvertently left out of the phrase following "legal action." Without this phrase, it might appear as though any kind of legal action would be affected. Since it is not intended that this requirement unnecessarily inhibit a P&A system from pursuing legal actions, the phrase, in Federal or State courts, has been reinserted. In addition, the Department has added phrases under (d) to clarify the intent that no additional burden is imposed where no administrative remedies exist and that a system is permitted to seek legal action after exhausting administrative remedies. The Department feels that, as amended, the regulation is reasonable, particularly when read together with the sentence which addresses the issue of "reasonable time," and with paragraph (d) which states that the admonition does not apply to "any legal action instituted to prevent or eliminate imminent serious harm to an individual with mental illness" and with paragraph (e) which states that "the Act imposes no additional burden respecting exhaustion of remedies." For purposes of clarity, the Department has added language to paragraph (e) requiring that a "system shall be held to the standard of exhaustion of remedies provided under State and Federal law."

Section 51.33-51.40 Reserved

P&A Subpart D—Access to Records, Facilities and Individuals

Many respondents urged that the regulations make clear that these requirements supersede all State statutory and common law prohibitions concerning P&A system access to records and that nothing in this part should be construed to limit the authority of a P&A to gain access to records. The Department responds that State law must not diminish the required authority of the Act and the P&A system may exercise its authority under State law where the authority exceeds the authority required by the Act. This requirement is set forth under 51.31 "Conduct of P&A Activities."

Section 51.41 Access to records

Section 51.41(a)

For purposes of clarity and consistency, the section ensuring access to records by all authorized agents of a

system has been moved from 51.42(c) in the original NPRM and inserted here.

Section 51.41(b)

This paragraph was formerly section (a). All commentary submitted in response to items in former paragraph (a) are reproduced here as applicable to new paragraph (b). The definition of "Probable Cause" which formerly appeared as paragraph (b) in the NPRM has been moved to the Definitions section (51.2) for clarity and consistency and in response to many requests.

A large number of respondents believed that an incident of abuse or neglect should refer not only to a particular individual, but also to general conditions or problems that affect many or all individuals in a facility. They argued that neither the Act nor case law imposes an individual-specific probable cause requirement. The Department agrees and has provided for this under conduct of P&A activities in 51.31(g) by including general conditions affecting health or safety as well as in 51.41(b)(2)(iii) by including that a P&A system may determine that an individual with mental illness "may be" subject to abuse or neglect.

It was recommended by several commenters that the Department require a mandatory time frame of 3 days for the release of records, once authorization has been obtained, and that the P&A system be granted expedited access—24 hours—in certain emergency situations. They reported that uncooperative facilities have attempted to thwart an investigation by "sitting on" the records. The Department agrees that access must be provided promptly, and has inserted this in the regulation under paragraph (a). The Department does not wish to mandate a specific time frame for release of records but notes that Sections 51.32(c) and (d), which permit the system to seek legal action after exhausting administrative remedies, apply to circumstances regarding disputes concerning the delay or denial of access to records.

Section 51.41(b)(2)(ii)

A few respondents wanted clarification on whether permission from the guardian was necessary in order for a P&A system to access the records of a deceased person. They requested affirmation of their understanding that a P&A system may access records when, under State law, the relationship between a deceased person and a legal representative/guardian terminates at death. The Department responds that access to the records of a deceased person is governed by State law.

One respondent requested that the last phrase of this subparagraph be revised to clarify that neither State nor "one of its political subdivisions" may prohibit access to records. The Department agrees that the intent is to prohibit denial of access by the State or by any of its political subdivisions where there is probable cause and the State is the individual's guardian, and has added this language.

Sections 51.41(b)(3)(i) (ii) and (iii)

Many respondents noted that these subsections appear to require that the legal representative actually be contacted before a P&A system would be allowed to take independent action. They reported their experience that legal guardians often are unavailable for long periods of time, or refuse to communicate with the P&A system. The Department agrees that restricting the ability of the P&A system to act in circumstances when it has probable cause to believe that the health or safety of the individual with mental illness is in serious and immediate jeopardy and the legal representative is unavailable, would compromise the intent of this subsection, particularly in light of subparagraph (iii) which allows the P&A system to take action if the representative has filed or refused to act. The language will be changed to reflect the Department's intent that the system must have made a "good faith effort" but that contact is not required. P&A systems should be able to document efforts made to contact the representative of an individual and that these efforts are reasonably calculated to be effective in notifying the representative.

Section 1.41(c)

Many respondents noted that to conduct a full investigation, a P&A system should have access to all records whether written or retained in another medium, and whether draft or final document, including handwritten notes, video or audio tape recordings; electronic files or photographs; "daily happenings" sheets (changes in status, discharges, ward transfers); policy and procedures manuals maintained by a facility; court documents; emergency room records; quality assurance documents; personnel records; records of transporting entities; and physical and documentary evidence reviewed with related investigative findings. It is argued that without an opportunity to review information from various sources, there can be neither a full investigation nor a determination of whether the investigation of another agency or facility was sufficiently

thorough. The Department agrees that any or all of the above-named records may be considered relevant on a case-by-case basis, and that they all be considered under the current meaning of "records." The Department has incorporated a number of items which clarify the intention that all records are to be accessible, but it has not included every single example.

One commenter was concerned that the regulations appear to allow access to records which in a number of States are confidential by law. This individual argued that system access to records should be granted only when the request is in compliance with the requirements set by State statutes. Another felt that the regulations exceeded the authority provided in the statute and went well beyond certain State statutes by providing access to in-house incident reports, certification and licensing reports, facility self-assessment reports, and financial records. Another felt that the following records should be exempt: records protected by the attorney-client privilege; reports prepared by individuals and entities performing certification or licensure reviews; reports prepared by professional accreditation organizations; and related assessments prepared by the facility, its staff, contractors or related entities. The Department does not agree. It is clearly the intent of the Act that the system have full access to "all records of an individual" pertaining to a full investigation of a report or complaint. The only exception noted [Senate Report 102-114, 102nd Congress, 1st Sess. 5, 1991] is the Joint Commission on Accreditation of Hospitals Report—peer review/medical review records. In order for the P&A system to carry out its mandate to protect the rights of individuals with mental illness and to investigate allegations of abuse or neglect in public and private facilities, they must be empowered to access information contained in all records relevant to such activities. In all circumstances where there is a direct conflict these regulations will supersede State law unless State law gives greater access. However, the Department does not intend to preempt State statutes that protect from disclosure the records produced by medical care evaluation or peer review committees. In addition, where there is a State statute that requires certain procedures with respect to personnel records, the Department expects P&As to follow these procedures.

Several respondents supported the importance of including records which do not only relate to the individual who

is the object of a full investigation and felt it particularly important that the decision regarding which records are relevant be at the sole discretion of the system.

The Department agrees that the P&A system shall have "reasonable access" to all "relevant" records.

In order to be consistent with the Act at section 105(a)(4) that provides that a P&A shall "have access to all records of—any individual," and the DD regulations, the Department has inserted the word "individual" before records in paragraphs (c) and (c)(1). Several commenters recommended that the system representatives be authorized to access records which are not in the actual possession of the facility but which are relevant to a full investigation. The Department agrees that the intent of the Act is to enable system access to all relevant records and will insert language under (c)(1) to ensure access to records maintained by or in the possession of the provider's agency or stored or maintained by any other entities (whether or not such entities actually produced the records). In obtaining such records, the system shall ensure that it has obtained appropriate, and specific, consent consistent with the requirements of section 105(a)(4) of the Act. Also, the P&A shall request of facilities that in requesting records from service providers or other facilities on residents that they indicate in the release form the records may be subject to review by a system. This language has been inserted in paragraph (c)(1).

Section 51.41(c)(2)(iv)

Several respondents requested that the following information and records also be identified as accessible to the P&A: supporting information relied upon in creating a record, including all information and records used or reviewed in preparing reports of abuse, neglect, injury or violations of rights such as records which describe persons who were interviewed, physical and documentary evidence that was reviewed, and the related investigative findings. The Department agrees and has included this language in (c)(2)(iv) except that violations of rights are covered only to the extent that they fall into the definition of abuse.

Section 51.41(d)

Two commenters believed that the authority to access the records of any persons who might have knowledge about alleged abuse or neglect should be included under Access to Records. The Department agrees but notes that P&A systems should have only "reasonable

access" to such records and that access to records of facility service recipients be consistent with sections 105 and 106 of the Act. The Department has moved this section from 51.42(a)(3) to 51.41(d). What previously was (d) shall now be (e).

Section 51.41(e)

Two respondents mentioned that allowing a facility to charge fees for copying records imposes a financial strain on the P&A systems and asked that the regulations set limits to control these costs. In addition, they request that the regulations clarify that the system has the right to obtain and copy the actual records and not only to "inspect" records on site at the facility. The Department does not wish to specify fee limitations, however, it notes that the P&A system may not be charged more than is "reasonable" according to prevailing local rates, and certainly not a rate higher than that charged any other service provider. Nothing shall prevent a system from negotiating a lower fee or no fee. The Department agrees that these regulations do authorize the P&A system to have access to the actual records and to make copies; simply allowing a system to "view" or "inspect" records is not sufficient. Because of the insertion of (c) noted above, the Department has moved this section to 51.41(e).

Section 51.42 Access to Facilities and residents

Section 51.42(a)

For clarity, this section has been moved from (c) to (a) where the Department felt it more appropriate.

Section 51.42(b)

All comments received responsive to section (a) as published in the NPRM are addressed here under (b).

One respondent mentioned that it would be helpful if the regulations clarified that children's facilities are also covered by the access and confidentiality of information provisions. Access is often held up by providers until the P&A system can convince them of the requirement that all records and information are confidential. The Department responds that children's care and treatment facilities are covered by these regulations and that the confidentiality requirements also apply.

One commenter argued that the regulation should require mandatory access for conducting full investigations of abuse or neglect. The Department responds that "reasonable access" is sufficient and means during all hours and shifts and not only on week days during facility "business hours." Access

should be as prompt as necessary to conduct full investigations of abuse and neglect when an incident has been reported to the system or when the system has determined probable cause.

Two commenters believed that the authority to access the records of and interview any persons who might have knowledge about alleged abuse or neglect is too broad. The Department agrees in part that the authority is too broad pertaining to records, but not to interviews. The Department believes that the P&A has reasonable access and authority to interview and examine all relevant records of any facility service recipient (consistent with section 105 of the Act) or employee. The phrase "other person who might have knowledge of the alleged abuse or neglect" was deleted from this paragraph. Others urged that this authority also be included in the Access to Records provisions under section 51.41. The Department agrees and, with the caveats noted above, moved this authority to 51.41(d). Also, the Department added language to section 51.42(b) in conformity with the DD regulations indicating that as part of the access authority, the P&A has the opportunity to interview any facility service recipient, employee or other persons.

Several commenters suggested that P&A systems should not be required to provide notice to a facility that they are going to come to that facility to investigate an incident, and further, that P&A systems should be able to appear unannounced at a facility to investigate any report that is regarded as an emergency. The Department responds that the regulations do not require notice to be given a facility in advance of an investigation, but that in nonemergency instances such notice is reasonable. The Department agrees that in cases where a system believes that an individual with mental illness is, or may be, in imminent danger of serious harm, the system should investigate as quickly as possible and that, as written, the regulations do provide for prompt access.

Many commenters felt that P&A systems should have the right to access facilities "whenever necessary" to investigate alleged incidents of neglect and abuse. They maintained that reasonable access means access "at any and all times necessary" to conduct a full investigation of an incident, that the determination of "reasonableness" should reside with the P&A system, and the facility should be required to give access on request. If the facility wishes to contest the "reasonableness," they should be authorized to do so only after the access has been granted, not before.

The Department does not agree that the P&A system should have access at ALL times, but does accept the argument that access be granted "all times necessary * * *" to conduct a full investigation, and particularly when the system has determined "probable cause" that there is or may be imminent danger of serious abuse or neglect of an individual with mental illness. In addition, 51.42(c) provides for access to facility residents and to programs "at reasonable times, which at a minimum shall include normal working hours and visiting hours." Access should not be limited only to business hours during weekdays, and should be to all areas used by residents or accessible to residents. Access is afforded the system under this section at (c)(2) in order to monitor compliance with respect to the rights and safety of residents. Finally, the Department has inserted the definition of "Full Investigation" to mean the " * * * access to facilities, clients and records authorized under these regulations that is necessary for a P&A system to make a determination about whether an allegation of abuse or neglect is taking place or has taken place."

Several respondents wished the regulations to include a requirement that facility residents be provided with the name, address, and telephone number of the P&A, uncensored access to writing materials, and private access to a telephone, for contacting the P&A. The Department agrees that such conditions are reasonable and it shall be considered applicable in this section under paragraph (c)(1), as revised.

Two commenters believed that the authority to monitor compliance with patient rights is too broad. The Department disagrees; monitoring compliance with patient rights is an opportunity to prevent incidents from occurring and to ensure that facility staff, as well as residents, understand what their rights are.

Several respondents recommended that P&A access not be hindered by facilities through requirements that monitoring, training, tours or other activities at the facility take place only with advance notice or in the presence or company of facility staff. Such practices deny the P&A system the ability to monitor for health, safety or environmental violations, or to observe the general living conditions of the residents.

One respondent suggested that, in the case of an actively aggressive resident, the P&A staff should be permitted to observe the client from a safe distance to verify the situational need. It was suggested that the P&A system be

permitted to observe the client privately with the seclusion door open, to wait until the aggressive behavior has stopped, and to reschedule a visit at a time mutually agreeable to the parties, but not later than 48 hours and if the client is placed on one-to-one supervision, P&A staff should be permitted to observe or otherwise verify the behavior which calls for such supervision.

The Department responds that the intent of the regulations is to ensure that P&A systems have full unaccompanied access to residents and to all areas of the facility accessible to residents. In the interest of safety, access to certain nonpublic areas or to certain residents may be restricted by the facility but only in accordance with the procedures stipulated in section 51.43 (Denial or Delay of Access). The procedure for observation seems reasonable but the Department does not wish to provide detailed guidance in this instance for the conduct of P&A system activities. Policies and procedures should be developed by each P&A system itself to guide and coordinate advocacy activities.

One respondent suggested that the facility should make P&A literature, which explains P&A system services and the rights of the residents under the Act and other laws, available to residents and to legal guardians. Such materials should be made available upon admission to the facility and at regular intervals (at least quarterly) thereafter. The Department agrees that such literature should be available but cannot require facilities to do so. The Department notes that the P&A systems are to establish an ongoing presence in the facility and are authorized in this section under (c)(1) to provide information to residents.

Section 51.42(d)

Several commenters suggested that paragraph (d) be modified to specifically include persons who have legal guardians or conservators, arguing that the definition should be as expansive as possible in order to meet the clearly delineated purpose of the Act. One suggested that the regulations specify that, in response to a request for assistance from a minor or from an individual with a legal guardian, the P&A system may respond by visiting the requester, but may not institute formal negotiations. The Department agrees that such is the case and has added language to clarify that P&As have access to persons who have legal guardians, including both adults and minors, regardless of whether there is a State or local law or regulation which

restricts access to minors and adults with legal guardians. The Department has become aware of several situations where a state or local requirement stood as an impediment to providing general information to individuals or monitoring general conditions of facilities. In these situations, the facilities argued that the P&A could not have any formal access to such individuals prior to obtaining consent from the individual's guardian or conservator. In the Department's view this prevents the P&As from carrying out their statutorily mandated duties, by preventing them from speaking with, and monitoring conditions affecting the safety of, individuals who have legal guardians—including minors. Accordingly, the Department intends that these regulations shall preempt any State or local laws and regulations which prohibit access to such individuals without obtaining consent from the guardians and has added such language at 51.42(e). The Department notes, however, that the P&A system may take no action on behalf of individuals with legal guardians or conservators without appropriate consent, except in emergency situations as discussed above. In all cases, the Department encourages facilities to provide general notice to guardians regarding the responsibilities of the P&A system, and inform them that it is possible that the P&As may speak informally with residents regarding their rights as well as conditions affecting their health or safety. Also, the Department has inserted into this paragraph the requirement that the P&A shall make every effort to ensure that the parents of minors or guardians of individuals in the care of a facility are informed that the system will be monitoring activities at the facility and may in the course of such monitoring have access to the minor or adult with a legal guardian.

Although the regulations address the issue of privacy, many respondents felt that they should be strengthened to ensure private communications and unaccompanied access to clients, without having to provide a justification to the facility. It is felt that only by frequent personal contact, without the presence of institutional staff, can the P&A system effectively carry out its mission of protecting the rights and safety of residents. The Department agrees that private and unaccompanied access to clients and other residents should be provided and that, if denied, justification should be required under 51.43. The regulations incorporate a provision which specifies that the

system generally shall be permitted unaccompanied access to meet and communicate privately with individuals, informally or formally, without the presence of facility staff.

Section 51.42(f)

In response to Department comments section 51.44 Access to Federal facilities and records in the original NPRM has been moved here. This change is to consolidate access requirements regarding facilities and records.

Several commenters argued that there is no reason to differentiate Federal from State facilities and that this section be deleted. One commenter suggested that the section be reworded to read: "a system providing representation to individuals with mental illness in Federal facilities shall be accorded the same rights and authority accorded to that system in other public and private facilities." The Department disagrees. Principles of statutory interpretation require that Federal facilities be excluded if not specifically included. Congress clearly intended that there be a differentiation. The regulatory language is taken exactly from the 1991 amendments to the Act and the Department has no justifiable reason to change it through regulation.

Section 51.43 Denial or Delay of Access

The title of this section has been changed to accommodate recommendations received in the commentary regarding delay of access.

Several commenters argued that the section on denial of access serves no useful purpose, is addressed in the Resolving Disputes section, and should be deleted. The Department does not agree. Commenters expressed concern that this section would routinely invite denial or delay of access by facilities. The Department understands the concern, but responds that if and when access is denied to records, facilities and residents, it is critical that the P&A be protected from dealing with lengthy denial processes; therefore, this section requiring that a facility provide a *prompt* written justification when denying access will remain.

It was argued by several respondents that P&A systems should not have to provide any justification of their need to access the name, address and phone number of guardians, conservators or other legal representatives and that systems should have easy access to such information. If access is denied, the commenters recommend that the facility be required to provide written justification for the denial as promptly as possible, and no longer than three

days. The Department agrees that the system has no requirement to provide justification concerning their need for access to information regarding guardians, conservators or legal representatives and that this information should be provided promptly. The regulation includes the word "prompt," but the Department feels that a time-specific definition of "promptness" is not a matter for regulation.

Some commenters alleged that facilities often deny unaccompanied access to a resident when the authorized mental health professional determines it "necessary for treatment purposes;" they argue that such denial of access should be allowed only for specified, limited, and reasonable periods of time, and that the reasons for it should be noted in the resident's treatment plan. Additionally, they wanted the P&A system to be provided documentation in writing, to include the reasons for the denial of access to the resident. Others believed that a mental health professional should never be able to deny an individual with mental illness access to their attorney. The Department notes these concerns and responds that all denials of access are subject to the conditions of this subsection.

Section 51.45 Confidentiality of Protection and Advocacy System Records

For purposes of clarity, this section will apply to all records maintained in the possession of the system, and not only to "client" records. The word "Client" has been dropped from the title.

Two commenters noted that the confidentiality requirements proposed in this section are inconsistent with parallel requirements applicable under the DD Act and the Protection and Advocacy for Individual Rights program. The argument which these respondents made was that Congress intended that the parallel requirements of the three programs be applied in a consistent manner. The Department agrees and has made changes to these regulations to conform with the ADD regulatory language to establish uniform requirements.

Others asked that these requirements be applicable both to persons whom the system views as its "client" and to persons who have merely been provided general information or technical assistance by the system. The Department agrees and has added language under subparagraph (a)(1)(ii) and (3) of this section.

One commenter believed that a person or entity receiving information

from a P&A system should be advised of its confidential nature. This is particularly important when such information is being released to third parties. All clients should be told prior to consenting to release information that it may be disclosed to third parties in certain instances. The Department responds that these regulations require each P&A system to establish such policies with regard to release of information concerning clients and has addressed this under sections 51.45 (a)(2) and (a)(3).

One commenter stated that the principles of attorney-client privilege should generally govern P&A system confidentiality requirements. Such requirements should include a provision that the confidentiality requirements extend not just to clients, but to anyone who contacts a P&A system seeking advice or assistance. The Department agrees and has included regulatory language to address this under (a)(1)(ii) and (3).

One commenter believed that section 106(a) of the Act was intended to ensure that the system maintain the confidentiality of records in compliance with applicable State, Federal, and local laws and with the rules of any involved organization or institution which has legal responsibility for the records. The actual language of that sections states that "an eligible system which * * * has access to records which, under Federal or State law, are required to be maintained in a confidential manner by a provider of mental health services shall * * * maintain the confidentiality of such records to the same extent as it required of the provider of such service." The Department has inserted "under Federal or State laws" at (a)(1)(i) in this section to clarify the issue. The Department requires that the highest standards of confidentiality be maintained so that all parties are assured of and have confidence in the security of the confidentiality of any records released to the P&A system.

Several commenters stated that confidentiality is essential and that the P&A system must be able to assure clients and informants that they will not reveal information about their cases or identities of clients. The Department agrees that confidentiality is essential but notes that a system may not provide complete and absolute assurance that no confidential materials will ever be viewed by other parties—albeit under the same strictures of obligation to confidentiality. The Department has added language under (a)(1)(iii) and (a)(3) in conformity with ADD regulations, to keep confidential the identity of individuals who report

incidents of abuse and neglect and of individuals who furnish information that forms the basis for a probable cause determination.

For purposes of clarity, the paragraph that starts after (b)(2) "For purposes of any periodic audit * * *" and the following paragraph have been labeled paragraph (c) and (d) and moved to the end of section 51.45. One respondent was concerned that the language may be interpreted as giving investigative and enforcement agencies access to client records if such agencies have been called in to investigate a complaint against the P&A system. The Department responds that these regulations allow excess to client records in very limited circumstances and only to the Department and other authorized Federal or State officials for purposes of audit or for monitoring system compliance with applicable Federal or State laws and regulations. The purpose of obtaining information from client files is to determine whether P&A systems are spending grant funds appropriately. Official that have access to such information must keep it confidential to the maximum extent permitted by law and regulations. In response to comments received and to conform with the ADD regulations, the Department has inserted under paragraph (c) respecting the disclosure, under certain circumstances, of confidential information to Federal and State officials. This language clarifies that the purpose of obtaining personally identifiable client information is solely to determine that P&A systems are spending Federal grant funds in conformity with the Act and these regulations. Language has been included to indicate that officials who have access to such information must keep it confidential to the maximum extent permitted by law and regulations.

One commenter had concerns about the relationship between the confidentiality provisions of these regulations and those which are applicable to alcohol and other drug treatment records. The Department notes that this is a significant issue that is beyond and outside of the scope of these regulations and will require resolution within the context of 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records." The conflict arises when consent cannot be obtained for the release of confidential information either because the person is not competent and does not have a guardian or because the person cannot be located. Under such circumstances the P&A system would have to petition the courts for an order to obtain the records. The Department has no

response at this time and welcomes further commentary on this issue for consideration. Some respondents argued that there should be an absolute and clear Federal standard of confidentiality, one which does not refer to rules applicable to mental health service providers in a particular State. The Department responds that there currently is no Federal standard regarding the confidentiality of general medical records. Because most States have statutory requirements governing confidentiality of patient records, the Department does not wish to impose different requirements in this area.

Section 51.46 Disclosing Information Obtained From a Provider of Mental Health Services

Two commenters noted the error in the last sentence of paragraph (a) which states that such determination shall be provided at the time that the system's access to the information is "denied." To correct this error, the word "granted" will be substituted for the word "denied."

Impact Analysis

Executive Order 12866

Executive Order 12866 requires that regulations be reviewed to ensure that they are consistent with the priorities and principles set forth in the Executive Order. The Department has determined that this rule is consistent with these priorities and principles. An assessment of the costs and benefits of available regulatory alternatives (including not regulating) demonstrated that the approach taken in the regulation is the most cost-effective and least burdensome while still achieving the regulatory objectives.

This final rule implements the 1991 reauthorization for the Protection and Advocacy for Mentally III Individuals Act of 1986 (Act) 42 U.S.C. 10801 *et seq.*). The regulations provide guidance on the implementation of authorized activities P&A systems to protect and advocate the rights of individuals with mental illness. These are final rules to implement Titles I and III of the Act, as amended. Authorized activities include investigation of incidents of abuse and neglect and the pursuit of legal, administrative and other appropriate remedies to ensure the protection of the rights of individuals with mental illness in facilities providing care or treatment. The regulations provide basic definitions and clarify the requirements of the Act.

The Department estimates that these regulations will not result in additional cost to the Federal Government, the

States, universities and any other organizations to which they may apply.

Regulatory Flexibility Act of 1980

Consistent with the Regulatory Flexibility Act [5 U.S.C. Ch. 6], the Department tries to anticipate and reduce the impact of rules and paperwork requirements on small businesses. For each rule with a "significant economic impact on a substantial number of small entities," an analysis describing the rule's impact on small entities is prepared. The primary impact of these regulations is on the States, which are not "small entities" within the meaning of the Act. However, they will affect small private institutions providing services to individuals with mental illness. This impact will be minimal in that the

institutions will simply be subject to review at no cost when a complaint is made against them. For these reasons, the Secretary certifies that these rules will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

This final rule contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104-13). The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the

data needed, and completing and reviewing the collection of information.

Title: Protection and Advocacy of Individuals with Mental Illness—42 CFR Subchapter 51—FINAL RULE.

Description: Data to be reported are required by 42 U.S.C. 10805 and 10821 and will be used by the Secretary to determine grantee eligibility for allotments and to evaluate compliance with the Act. Additionally, data will be collected to publish annual reports that are submitted to the President, the Congress, and the National Council on Disabilities as required by 42 U.S.C. 10824 of the Act and 42 U.S.C. 6006 of the DD Act.

Description of respondents: Private and public grantees.

Estimated Annual Reporting Burden:

	Annual number of respondents	Annual frequency	Average burden per response (hours)	Annual burden hours
Section 51.8 Program Performance Report:	56	1		
Part I			33	
Part II			2	
(Subtotal)			(35)	1,960
Section 51.8 Advisory Council Report	56	1	10	560
Section 51.10 Remedial Actions:				
Corrective Action Plan	6	1	8	48
Implementation Status Report	6	3	2	36
Section 51.23(c) Reports, materials and fiscal data to Advisory Council	56	1	1	56
Section 51.25(b)(2) Grievance Procedure	56	1	.5	28
Total				2,688

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Substance Abuse and Mental Health Services Administration is providing the public with the opportunity to comment on the information collection requirements contained in this final rule. In order to fairly evaluate whether a collection of information should be approved by the Office of Management and Budget (OMB), the Paperwork Reduction Act requires that we solicit comments on:

- whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility;
- the accuracy of the Agency's estimate of the burden of the proposed collection of information;
- ways to enhance the quality, utility, and clarity of the information to be collected; and
- ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments on the Paperwork requirement of this regulation should be sent to: Daniel J. Chenok, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10236, Washington, DC 20503. Written comments should be received within 60 days of this notice.

List of Subjects in 42 CFR Part 51

Administrative practice and procedure, Grant programs—health programs, Grant programs—social programs, Health records, Mental health programs, Privacy, Reporting and recordkeeping requirements.

Dated: October 2, 1997.

Donna E. Shalala,
Secretary.

Accordingly, part 51 is added to title 42 of the Code of Federal Regulations to read as follows:

PART 51—REQUIREMENTS APPLICABLE TO THE PROTECTION AND ADVOCACY FOR INDIVIDUALS WITH MENTAL ILLNESS PROGRAM

Sec.

51.1 Scope.

51.2 Definitions.

Subpart A—Basic Requirements

51.3 Formula for determining allotments.

51.4 Grants administration requirements.

51.5 Eligibility for allotment.

51.6 Use of allotments.

51.7 Eligibility for protection and advocacy services.

51.8 Annual reports.

51.9 [Reserved]

51.10 Remedial actions.

51.11–51.20 [Reserved]

Subpart B—Program Administration and Priorities

51.21 Contracts for program operations.

51.22 Governing authority.

51.23 Advisory council.

51.24 Program priorities.

51.25 Grievance procedure.

51.26 Conflicts of interest.

51.27 Training.

51.28–51.30 [Reserved]

Subpart C—Protection and Advocacy Services

- 51.31 Conduct of protection and advocacy activities.
 51.32 Resolving disputes.
 51.33–51.40 [Reserved]

Subpart D—Access to Records, Facilities and Individuals

- 51.41 Access to records.
 51.42 Access to facilities and residents.
 51.43 Denial or delay of access.
 51.44 [Reserved]
 51.45 Confidentiality of protection and advocacy system records.
 51.46 Disclosing information obtained from a provider of mental health services.

Authority: 42 U.S.C. 10801, *et seq.*

§ 51.1 Scope.

The provisions of this part apply to recipients of Federal assistance under the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended.

§ 51.2 Definitions.

In addition to the definitions in section 102 of the Act, as amended, the following definitions apply:

Abuse means any act or failure to act by an employee of a facility rendering care or treatment which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to an individual with mental illness, and includes but is not limited to acts such as: rape or sexual assault; striking; the use of excessive force when placing an individual with mental illness in bodily restraints; the use of bodily or chemical restraints which is not in compliance with Federal and State laws and regulations; verbal, nonverbal, mental and emotional harassment; and any other practice which is likely to cause immediate physical or psychological harm or result in long-term harm if such practices continue.

Act means the Protection and Advocacy for Mentally Ill Individuals Act of 1986, as amended, also referred to as Protection and Advocacy for Individuals with Mental Illness Act.

ADD means the Administration on Developmental Disabilities within the Administration for Children and Families, Department of Health and Human Services.

Care or Treatment means services provided to prevent, identify, reduce or stabilize mental illness or emotional impairment such as mental health screening, evaluation, counseling, biomedical, behavioral and psychotherapies, supportive or other adjunctive therapies, medication supervision, special education and

rehabilitation, even if only “as needed” or under a contractual arrangement.

Center or **CMHS** means the Center for Mental Health Services, a component of the Substance Abuse and Mental Health Services Administration.

Complaint includes, but is not limited to any report or communication, whether formal or informal, written or oral, received by the P&A system, including media accounts, newspaper articles, telephone calls (including anonymous calls) from any source alleging abuse or neglect of an individual with mental illness.

Department or **HHS** means the U.S. Department of Health and Human Services.

Designated Official is the State official or public or private entity empowered by the Governor or State legislature to be accountable for the proper use of funds by the P&A system.

Director means the Director of the Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, or his or her designee.

Facility includes any public or private residential setting that provides overnight care accompanied by treatment services. Facilities include, but are not limited to the following: general and psychiatric hospitals, nursing homes, board and care homes, community housing, juvenile detention facilities, homeless shelters, and jails and prisons, including all general areas as well as special mental health or forensic units.

Fiscal Year or **FY** means the Federal fiscal year (October 1–September 30) unless otherwise specified.

Full Investigation is based upon a complaint or a determination of probable cause and means the access to facilities, clients and records authorized under this part that is necessary for a P&A system to make a determination about whether an allegation of abuse or neglect is taking place or has taken place. Full investigations may be conducted independently or in cooperation with other agencies authorized to conduct similar investigations.

Governor means the chief executive officer of the State, Territory or the District of Columbia, or his or her designee, who has been formally designated to act for the Governor in carrying out the requirements of the Act and this part.

Individual with Mental Illness means an individual who has a significant mental illness or emotional impairment, as determined by a mental health professional qualified under the laws and regulations of the State and

(1) Who is an inpatient or resident in a facility rendering care or treatment, even if the whereabouts of such inpatient or resident is unknown;

(2) Who is in the process of being admitted to a facility rendering care or treatment, including persons being transported to such a facility, or

(3) Who is involuntarily confined in a detention facility, jail or prison.

Legal Guardian, Conservator, and Legal Representative all mean an individual whose appointment is made and regularly reviewed by a State court or agency empowered under State law to appoint and review such officers, and having authority to consent to health/mental health care or treatment of an individual with mental illness. It does not include persons acting only as a representative payee, persons acting only to handle financial payments, attorneys or persons acting on behalf of an individual with mental illness only in individual legal matters, or officials responsible for the provision of health or mental health services to an individual with mental illness, or their designees.

Neglect means a negligent act or omission by an individual responsible for providing services in a facility rendering care or treatment which caused or may have caused injury or death to an individual with mental illness or which placed an individual with mental illness at risk of injury or death, and includes, but is not limited to, acts or omissions such as failure to: establish or carry out an appropriate individual program or treatment plan (including a discharge plan); provide adequate nutrition, clothing, or health care; and the failure to provide a safe environment which also includes failure to maintain adequate numbers of appropriately trained staff.

Private Entity means a nonprofit or for-profit corporation, partnership or other nongovernmental organization.

Probable cause means reasonable grounds for belief that an individual with mental illness has been, or may be at significant risk of being subject to abuse or neglect. The individual making such determination may base the decision on reasonable inferences drawn from his or her experience or training regarding similar incidents, conditions or problems that are usually associated with abuse or neglect.

Program means activities carried out by the P&A system and operating as part of a P&A system to meet the requirements of the Act.

Public Entity means an organizational unit of a State or local government or a quasi-governmental entity with one or more governmental powers.

System means the organization or agency designated in a State to administer and operate a protection and advocacy program under Part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041, 6042) and thereby eligible to administer a program for individuals with mental illness.

Subpart A—Basic Requirements

§ 51.3 Formula for determining allotments.

The Secretary shall make allotments to eligible Systems from amounts apportioned each year under the Act on the basis of a formula prescribed by the Secretary in accordance with the requirements of sections 112 and 113 of the Act (42 U.S.C. 10822 and 10823).

§ 51.4 Grants administration requirements.

The following parts of titles 42 and 45 CFR apply to grants funded under this part.

- 42 CFR Part 50, Subpart D.
- 45 CFR Part 16—Procedures of the Departmental Grant Appeal Board.
- 45 CFR Part 74—Administration of Grants.
- 45 CFR Part 75—Informal Grant Appeals Procedures.
- 45 CFR Part 76—Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace.
- 45 CFR Part 80—Nondiscrimination under Programs Receiving Federal Assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964.
- 45 CFR Part 81—Practice and Procedure for Hearings under Part 80 of This Title.
- 45 CFR Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance.
- 45 CFR Part 86—Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving Federal Financial Assistance.
- 45 CFR Part 91—Nondiscrimination on the Basis of Age in Education Programs and Activities Receiving Federal Financial Assistance from HHS.
- 45 CFR Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.
- 45 CFR Part 93—New Restrictions on Lobbying.
- 45 CFR Part 1386, subpart A.

§ 51.5 Eligibility for allotment.

(a) Federal financial assistance for protection and advocacy activities for individuals with mental illness will be given only to a System that has been established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041, *et seq.*) and designated in accordance with 45 CFR part 1386, subpart B.

(b) The P&A system must meet the requirements of sections 105 and 111 of the Act (42 U.S.C. 10805 and 10821) and that P&A system must be operational. Each system shall submit an application at the beginning of each PAIMI authorization period. This application shall contain at a minimum the program priorities and budget for the first year of the authorization period and the required assurances and certifications. Thereafter, the system shall submit yearly updates of the budget and program priorities for the upcoming fiscal year through its annual report.

(c) Written assurances of compliance with sections 105 and 111 of the Act (42 U.S.C. 10805 and 10821) and other requirements of the Act and this part shall be submitted by the P&A system in the format designated by the Director. These assurances will remain in effect for the period specified in the application for funds unless changes occur within the State which affect the functioning of the P&A system, in which case an amendment will be required 30 days prior to the effective date of the change. The P&A system shall also provide the Department the name of the designated official.

(d) The Governor's written assurance that the allotments made available under the Act will be used to supplement and not to supplant the level of non-Federal funds available in the State to protect and advocate the rights of individuals with mental illness shall be submitted by the P&A system. The Governor may provide this assurance along with the assurances provided to ADD under 45 CFR part 1386, as long as it can reasonably be construed as applying to the PAIMI program. Any future "supplement and not supplant" assurance shall explicitly refer to the PAIMI program.

§ 51.6 use of allotments.

(a) Allotments must be used to supplement and not to supplant the level of non-Federal funds available in the State to protect and advocate the rights of individuals with mental illness.

(b) Allotments may not be used to support lobbying activities to influence proposed or pending Federal legislation or appropriations. This restriction does not affect the right of any P&A system, organization or individual to petition Congress or any other government body or official using other resources.

(c) Allotments may not be used to produce or distribute written, audio or visual materials or publicity intended or designed to support or defeat any candidate for public office.

(d) If an eligible P&A system is a public entity, that P&A system shall not be required by the State to obligate more than five percent of its annual allotment for State oversight administrative expenses under this grant such as costs of internal or external evaluations, monitoring or auditing. This restriction does not include:

- (1) Salaries, wages and benefits of program staff;
- (2) Costs associated with attending governing board or advisory council meetings; or
- (3) Expenses associated with the provision of training or technical assistance for staff, contractors, members of the governing board or advisory council.

(e) No more than ten percent of each annual allotment may be used for providing technical assistance and training, including travel expenses for staff, contractors, or members of the governing board or advisory council as defined in § 51.27.

(f) Allotments may be used to pay the otherwise allowable costs incurred by a P&A system in bringing lawsuits in its own right to redress incidents of abuse or neglect, discrimination, and other rights violations impacting on individuals with mental illness and when it appears on behalf of named plaintiffs or a class of plaintiffs for such purposes.

§ 51.7 Eligibility for protection and advocacy services.

In accordance with section 105(a)(1)(C) of the Act (42 U.S.C. 10805(a)(1)(C)) and the priorities established by the P&A system governing authority, together with the advisory council, pursuant to section 105(c)(2)(B) of the Act (42 U.S.C. 10805(c)(2)(B)), allotments may be used:

(a) To provide protection and advocacy services for:

(1) Individuals with mental illness as defined in 42 U.S.C. 10802(4) and 10805(a), including persons who report matters which occurred while they were individuals with mental illness;

(2) Persons who were individuals with mental illness who are residents of the State, but only with respect to matters which occur within 90 days after the date of the discharge of such individuals from a facility providing care or treatment; and

(3) Individuals with mental illness in Federal facilities rendering care or treatment who request representation by the eligible P&A system. Representation may be requested by an individual with mental illness, or by a legal guardian, conservator or legal representative.

(b) To provide representation of clients in civil commitment proceedings if the P&A system is acting on behalf of an eligible individual to obtain judicial review of his or her commitment in order to appeal or otherwise challenge acts or omissions which have subjected the individual to abuse or neglect or otherwise violated his or her rights. This restriction does not prevent a P&A system from representing clients in commitment or recommitment proceedings using other resources so long as this representation does not conflict with responsibilities under the Act.

§ 51.8 Annual reports.

By January 1 of each year, a report shall be submitted, pursuant to section 105(a)(7) of the Act (42 U.S.C. 10805(a)(7)), to the Secretary which is in the format designated by the Secretary.

§ 51.9 [Reserved]

§ 51.10 Remedial actions.

Failure to submit an annual report in the designated format on time or to submit requested information and documentation, corrective action plans and ongoing implementation status reports in response to Federal review and monitoring activities or to satisfy any other requirement of the Act, this part, or other requirements, may be considered a breach of the terms and conditions of the grant award and may require remedial action, such as the suspension or termination of an active grant, withholding of payments or converting to a reimbursement method of payment. Any remedial actions shall be taken consistent with 45 CFR Part 74 and 42 CFR Part 50, as appropriate.

§§ 51.11–51.20 [Reserved]

Subpart B—Program Administration and Priorities

§ 51.21 Contracts for program operations.

(a) An eligible P&A system should work cooperatively with existing advocacy agencies and groups and, where appropriate, consider entering into contracts for protection and advocacy services with organizations already working on behalf of individuals with mental illness. Special consideration should be given to contracting for the services of groups run by individuals who have received or are receiving mental health services or by family members of such individuals.

(b) An eligible P&A system may contract for the operation of all or part of its program with another public or private nonprofit organization with demonstrated experience in working

with individuals with mental illness provided that:

(1) Any organization that will operate the full program meets the requirements of section 104(a)(1), 105 and 111 of the Act (42 U.S.C. 10804(a)(1), 10805 and 10821) and has the capacity to perform protection and advocacy activities throughout the State;

(2) The eligible P&A system institutes oversight and monitoring procedures which ensure that this system will be able to meet all applicable terms, conditions and obligations of the Federal grant;

(3) The eligible P&A system and the contractor organization enter into a written agreement that includes at least the following:

(i) A description of the protection and advocacy services to be provided;

(ii) The type of personnel, their qualifications and training;

(iii) The methods to be used;

(iv) A timetable for performance;

(v) A budget;

(vi) Assurances that the contractor will meet all applicable terms and conditions of the grant;

(vii) Assurances that the contractor has adequate management and fiscal systems in place, including insurance coverage, if appropriate;

(viii) Assurances that the contractor's staff is trained to provide advocacy services to and conduct full investigations on behalf of individuals with mental illness; and

(ix) Assurances that the contractor staff is trained to work with family members of clients served by the P&A system where the clients are:

(A) Minors;

(B) Legally competent and choose to involve the family member; or,

(C) Legally incompetent and the legal guardians, conservators or other legal representatives are family members.

§ 51.22 Governing authority.

(a) Each P&A system shall have a governing authority responsible for its planning, designing, implementing and functioning. It shall, jointly with the advisory council, annually establish program priorities and policies.

(b) If the P&A system is organized with a multi-member governing board:

(1) Each P&A system shall establish policies and procedures for the selection of its governing board members and for the board evaluation of the P&A system director. The terms of board members shall be staggered and for 4 years except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. A member who has been appointed for a term of 4 years may not be reappointed

to the governing board during the 2-year period beginning on the date on which such 4-year term expired.

(2) The board shall be composed of members who broadly represent or are knowledgeable about the needs of the clients served by the P&A system and shall include a significant representation of individuals with mental illness who are, or have been eligible for services, or have received or are receiving mental health services, and family members, guardians, advocates, or authorized representatives of such individuals.

(3) If the governing authority is organized as a private nonprofit entity, the chairperson of the advisory council shall be a member of the governing board.

(c) Continuing efforts shall be made to include members of racial and ethnic minority groups as board members.

(d) Any member of the advisory council may also serve on the governing board.

§ 51.23 Advisory council.

(a) Each P&A system shall establish an advisory council to:

(1) Provide independent advice and recommendations to the system.

(2) Work jointly with the governing authority in the development of policies and priorities.

(3) Submit a section of the system's annual report as required under § 51.8.

(b) Members of the council shall include attorneys, mental health professionals, individuals from the public who are knowledgeable about mental illness, the advocacy needs of persons with mental illness and have demonstrated a substantial commitment to improving mental health services, a provider of mental health services, individuals who have received or are receiving mental health services and family members of such individuals. Continuing efforts shall be made to include members of racial and ethnic minority groups on the advisory council.

(1) At least 60 percent of the membership of the advisory council shall be comprised of individuals who have received or are receiving mental health services or who are family members of such individuals. At least one family member shall be a primary care giver for an individual who is currently a minor child or youth who is receiving or has received mental health services;

(2) The council shall be chaired by an individual who has received or is receiving mental health services or who is a family member of such an individual;

(3) The advisory council shall meet no less than three times annually. The terms of council members shall be staggered and for 4 years except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. A member who has been appointed for a term of 4 years may not be reappointed to the council during the 2-year period beginning on the date on which such 4-year term expired.

(c) Each P&A system shall provide its advisory council with reports, materials and fiscal data to enable review of existing program policies, priorities and performance outcomes. Such submissions shall be made at least annually and shall report expenditures for the past two fiscal years, as well as projected expenses for the next fiscal year, identified by budget category (e.g., salary and wages, contract for services, administrative expenses) including the amount allotted for training of each the advisory council, governing board and staff.

(d) Reimbursement of expenses. (1) Allotments may be used to pay for all or a part of the expenses incurred by members of the advisory council in order to participate in its activities. Expenses may include transportation costs, parking, meals, hotel costs, per diem expenses, stipends or subsistence allowances, and the cost of day care or child care (or its equivalent for the child's travel and subsistence expenses) for their dependents with mental illness or developmental disabilities.

(2) Each P&A system shall establish its own policies and procedures for reimbursement of expenses of council members, taking into account the needs of individual council members, available resources, and applicable restrictions on use of grant funds, including the restrictions in §§ 51.31(e) and 51.6(e).

§ 51.24 Program priorities.

(a) Program priorities and policies shall be established annually by the governing authority, jointly with the advisory council. Priorities shall specify short-term program goals and objectives, with measurable outcomes, to implement the established priorities. In developing priorities, consideration shall be given to, at a minimum, case selection criteria, the availability of staff and monetary resources, and special problems and cultural barriers faced by individuals with mental illness who are multiply handicapped or who are members of racial or ethnic minorities in obtaining protection of their rights. Systemic and legislative activities shall also be addressed in the development

and implementation of program priorities.

(b) Members of the public shall be given an opportunity, on an annual basis, to comment on the priorities established by, and the activities of, the P&A system. Procedures for public comment must provide for notice in a format accessible to individuals with mental illness, including such individuals who are in residential facilities, to family members and representatives of such individuals and to other individuals with disabilities. Procedures for public comment must provide for receipt of comments in writing or in person.

§ 51.25 Grievance procedure.

(a) The P&A system shall establish procedures to address grievances from:

(1) Clients or prospective clients of the P&A system to assure that individuals with mental illness have full access to the services of the program; and

(2) Individuals who have received or are receiving mental health services in the State, family members of such individuals, or representatives of such individuals or family members to assure that the eligible P&A system is operating in compliance with the Act.

(b) At a minimum, the grievance procedures shall provide for:

(1) An appeal to the governing authority from any final staff review and/or determination; in cases where the governing authority is the director of the P&A system, the final review and/or determination shall be made by a superior of the governing authority, e.g., a supervisor, or by an independent entity, e.g., an appointed board or committee.

(2) Reports, at least annually, to the governing authority and the advisory council describing the grievances received and processed and their resolution;

(3) Identification of individuals responsible for review;

(4) A timetable to ensure prompt notification concerning the grievance procedure to clients, prospective clients or persons denied representation, and to ensure prompt resolution;

(5) A written response to the grievant; and

(6) Protection of client confidentiality.

§ 51.26 Conflicts of interest.

The P&A system must develop appropriate policies and procedures to avoid actual or apparent conflict of interest involving clients, employees, contractors and subcontractors, and members of the governing authority and advisory council, particularly with

respect to matters affecting client services, particular contracts and subcontracts, grievance review procedures, reimbursements and expenses, and the employment or termination of staff.

§ 51.27 Training.

A P&A system shall provide training for program staff, and may also provide training for contractors, governing board and advisory council members to enhance the development and implementation of effective protection and advocacy services for individuals with mental illness, including at a minimum:

(a)(1) Training of program staff to work with family members of clients served by the program where the individual with mental illness is:

(i) A minor,

(ii) Legally competent and chooses to involve the family member; or

(iii) Legally incompetent and the legal guardian, conservator or other legal representative is a family member.

(2) This training may be provided by individuals who have received or are receiving mental health services and family members of such individuals.

(b) Training to enhance sensitivity to and understanding of individuals with mental illness who are members of racial or ethnic minorities and to develop strategies for outreach to those populations.

(c) Training to conduct full investigations of abuse or neglect.

§§ 51.28–51.30 [Reserved]

Subpart C—Protection and Advocacy Services

§ 51.31 Conduct of protection and advocacy activities.

(a) Consistent with State and Federal law and the canons of professional ethics, a P&A system may use any appropriate technique and pursue administrative, legal or other appropriate remedies to protect and advocate on behalf of individuals with mental illness to address abuse, neglect or other violations of rights.

(b) A P&A system shall establish policies and procedures to guide and coordinate advocacy activities. The P&A system shall not implement a policy or practice restricting the remedies which may be sought on behalf of individuals with mental illness or compromising the authority of the P&A system to pursue such remedies through litigation, legal action or other forms of advocacy. However, this requirement does not prevent the P&A system from placing limitations on case or client acceptance criteria developed as part of the annual

priorities. Prospective clients must be informed of any such limitations at the time they request service.

(c) Wherever possible, the program should establish an ongoing presence in residential mental health care or treatment facilities, and relevant hospital units.

(d) Program activities should be carried out in a manner which allows program staff to:

(1) Interact regularly with those individuals who are current or potential recipients of protection and advocacy services;

(2) Interact regularly with staff providing care or treatment;

(3) Obtain information and review records; and

(4) Communicate with family members, social and community service workers and others involved in providing care or treatment.

(e) A P&A system may support or provide training, including related travel expenses, for individuals with mental illness, family members of such individuals, and other persons who are not program staff, contractors, or board or council members, to increase knowledge about protection and advocacy issues, to enhance leadership capabilities, or to promote Federal-State and intra-State cooperation on matter related to mental health system improvement. Decisions concerning the selection of individuals to receive such training shall be made in accordance with established policies, procedures and priorities of the P&A system.

(f) A P&A system may monitor, evaluate and comment on the development and implementation of Federal, State and local laws, regulations, plans, budgets, levies, projects, policies and hearings affecting individuals with mental illness as a part of federally funded advocacy activities. A P&A system shall carry out systemic advocacy—those efforts to implement changes in policies and practices of systems that impact persons with mental illness.

(g) Determination of “probable cause” may result from P&A system monitoring or other activities, including observation by P&A system personnel, and reviews of monitoring and other reports prepared by others whether pertaining to individuals with mental illness or to general conditions affecting their health or safety.

(h) A P&A which is a public P&A system shall be free from hiring freezes, reductions in force, prohibitions on staff travel, or other policies imposed by the State to the extent that such policies would impact program staff or activities funded with Federal dollars and would

prevent the P&A system from carrying out its mandates under the Act.

(i) A P&A system may exercise its authority under State law where the authority exceeds the authority required by the Act. However, State law must not diminish the required authority of the Act.

§ 51.32 Resolving disputes.

(a) Each P&A system is encouraged to develop and employ techniques such as those involving negotiation, conciliation and mediation to resolve disputes early in the protection and advocacy process.

(b) Disputes should be resolved whenever possible through nonadversarial process involving negotiation, mediation and conciliation. Consistent with State and Federal laws and canons of professional responsibility, family members should be involved in this process, as appropriate, where the individual with mental illness is:

(1) A minor,

(2) Legally competent and chooses to involve the family member, or

(3) Legally incompetent and the legal guardian, conservator or other legal representative is a family member or the legal guardian, conservator or other legal representative chose to involve the family member.

(c) A P&A system must exhaust in a timely manner all administrative remedies, where appropriate, prior to initiating legal action in a Federal or State court.

(d) Paragraph (c) of this section does not apply to any legal action instituted to prevent or eliminate imminent serious harm to an individual with mental illness nor does it apply in circumstances where administrative procedures do not exist. If in pursuing administrative remedies, the P&A system determines that any matter with respect to an individual with mental illness with not be resolved within a reasonable time, the P&A system may pursue alternative remedies, including initiating legal action.

(e) A P&A system shall be held to the standard of exhaustion of remedies provided under State and Federal law. The Act imposes no additional burden respecting exhaustion of remedies.

§§ 51.33–51.40 [Reserved]

Subpart D—Access to Records, Facilities and Individuals

§ 51.41 Access to records.

(a) Access to records shall be extended promptly to all authorized agents of a P&A system.

(b) A P&A system shall have access to the records of any of the following individuals with mental illness:

(1) An individual who is a client of the P&A system if authorized by that individual or the legal guardian, conservator or other legal representative.

(2) An individual, including an individual who has died or whose whereabouts is unknown to whom all of the following conditions apply:

(i) The individual, due to his or her mental or physical condition, is unable to authorize the P&A system to have access.

(ii) The individual does not have a legal guardian, conservator or other legal representative, or the individual's guardian is the State or one of its political subdivisions; and

(iii) A complaint or report has been received and the P&A system has determined that there is probable cause to believe that the individual has been or may be subject to abuse or neglect.

(3) An individual who has a legal guardian, conservator, or other legal representative, with respect to whom a complaint or report has been received by the P&A system and with respect to whom the P&A system has determined that there is probable cause to believe that the health or safety of the individual is in serious and immediate jeopardy, whenever all of the following conditions exist:

(i) The P&A system has made a good faith effort to contact the representative upon prompt receipt of the representative's name and address;

(ii) The P&A system has made a good faith effort to offer assistance to the representative to resolve the situation; and

(iii) The representative has failed or refused to act on behalf of the individual.

(c) Information and individual records, whether written or in another medium, draft or final, including handwritten notes, electronic files, photographs or video or audio tape records, which shall be available to the P&A system under the Act shall include, but not be limited to:

(1) Information and individual records, obtained in the course of providing intake, assessment, evaluation, supportive and other services, including medical records, financial records, and reports prepared or received by a member of the staff of a facility or program rendering care or treatment. This includes records stored or maintained in locations other than the facility or program as long as the system has obtained appropriate consent consistent with section

105(a)(4) of the Act. The system shall request of facilities that in requesting records from service providers or other facilities on residents that they indicate in the release form the records may be subject to review by a system.

(2) Reports prepared by an agency charged with investigating abuse, neglect, or injury occurring at a facility rendering care or treatment, or by or for the facility itself, that describe any or all of the following:

(i) Abuse, neglect, or injury occurring at the facility;

(ii) The steps taken to investigate the incidents;

(iii) Reports and records, including personnel records, prepared or maintained by the facility, in connection with such reports of incidents; or

(iv) Supporting information that was relied upon in creating a report, including all information and records used or reviewed in preparing reports of abuse, neglect or injury such as records which describe persons who were interviewed, physical and documentary evidence that was reviewed, and the related investigative findings.

(3) Discharge planning records.

(4) Reports prepared by individuals and entities performing certification or licensure reviews, or by professional accreditation organizations, as well as related assessments prepared for the facility by its staff, contractors or related entities, except that nothing in this section is intended to preempt State law protecting records produced by medical care evaluation or peer review committees.

(5) Professional, performance, building or other safety standards, demographic and statistical information relating to the facility.

(d) A P&A system shall have reasonable access and authority to interview and examine all relevant records of any facility service recipient (consistent with the provisions of section 105(a)(4) of the Act) or employee.

(e) A P&A system shall be permitted to inspect and copy records, subject to a reasonable charge to offset duplicating costs.

§ 51.42 Access to Facilities and residents.

(a) Access to facilities and residents shall be extended to all authorized agents of a P&A system.

(b) A P&A system shall have reasonable unaccompanied access to public and private facilities and programs in the State which render care or treatment for individuals with mental illness, and to all areas of the facility which are used by residents or are

accessible to residents. The P&A system shall have reasonable unaccompanied access to residents at all times necessary to conduct a full investigation of an incident of abuse or neglect. This authority shall include the opportunity to interview any facility service recipient, employee, or other persons, including the person thought to be the victim of such abuse, who might be reasonably believed by the system to have knowledge of the incident under investigation. Such access shall be afforded, upon request, by the P&A system when:

(1) An incident is reported or a complaint is made to the P&A system;

(2) The P&A system determines there is probable cause to believe that an incident has or may have occurred; or

(3) The P&A system determines that there is or may be imminent danger of serious abuse or neglect of an individual with mental illness.

(c) In addition to access as prescribed in paragraph (b) of this section, a P&A system shall have reasonable unaccompanied access to facilities including all area which are used by residents, are accessible to residents, and to programs and their residents at reasonable times, which at a minimum shall include normal working hours and visiting hours. Residents include adults or minors who have legal guardians or conservators. P&A activities shall be conducted so as to minimize interference with facility programs, respect residents' privacy interests, and honor a resident's request to terminate an interview. This access is for the purpose of:

(1) Providing information and training on, and referral to programs addressing the needs of individuals with mental illness, and information and training about individual rights and the protection and advocacy services available from the P&A system, including the name, address, and telephone number of the P&A system.

(2) Monitoring compliance with respect to the rights and safety of residents; and

(3) Inspecting, viewing and photographing all areas of the facility which are used by residents or are accessible to residents.

(d) Unaccompanied access to residents shall include the opportunity to meet and communicate privately with individuals regularly, both formally and informally, by telephone, mail and in person. Residents include minors or adults who have legal guardians or conservators.

(e) The right of access specified in paragraph (c) of this section shall apply despite the existence of any State or

local laws or regulations which restrict informal access to minors and adults with legal guardians or conservators. The system shall make very effort to ensure that the parents of minors or guardians of individuals in the care of a facility are informed that the system will be monitoring activities at the facility and may in the course of such monitoring have access to the minor or adult with a legal guardian. The system shall take no formal action on behalf of individuals with legal guardians or conservators, or initiate a formal attorney/client or advocate/client relationship without appropriate consent, except in emergency situations as described in § 51.41(b)(3).

(f) A P&A system providing representation to individuals with mental illness in Federal facilities shall have all the rights and authority accorded other representatives of residents of such facilities pursuant to State and Federal laws.

§ 51.43 Denial of delay or access.

If a P&A system's access to facilities, programs, residents or records covered by the Act or this part is delayed or denied, the P&A system shall be provided promptly with a written statement of reasons, including, in the case of a denial for alleged lack of authorization, the name, address and telephone number of the legal guardian, conservator, or other legal representative of an individual with mental illness. Access to facilities, records or residents shall not be delayed or denied without the prompt provision of written statements of the reasons for the denial.

§ 51.44 [Reserved]

§ 51.45 Confidentiality of protection and advocacy system records.

(a) Records maintained by the P&A system are the property of the P&A system which must protect them from loss, damage, tampering or use by unauthorized individuals. The P&A system must:

(1) Except as provided elsewhere in this section, keep confidential all records and information, including information contained in any automated electronic database pertaining to:

(i) Clients to the same extent as is required under Federal or State laws for a provider of mental health services;

(ii) Individuals who have been provided general information or technical assistance on a particular matter;

(iii) Identity of individuals who report incidents of abuse or neglect or furnish information that forms the basis for a

determination that probable cause exists; and

(iv) Names of individuals who are residents and provide information for the record.

(2) Have written policies governing access to, storage of, duplication and release of information from client records; and

(3) Obtain written consent from the client, if competent, or from his or her legal representative, from individuals who have been provided general information or technical assistance on a particular matter and from individuals who furnish reports or information that forms the basis for a determination of probable cause, before releasing information to individuals not otherwise authorized to receive it.

(b) Nothing in this subpart shall prevent the P&A system from: (1) Issuing a public report of the results of an investigation which maintains the confidentiality of the individuals listed in paragraph (a)(1) of this section or,

(2) Reporting the results of an investigation which maintains the confidentiality of individual service recipients to responsible investigative or enforcement agencies should an investigation reveal information concerning the facility, its staff, or employees warranting possible sanctions or corrective action. This information may be reported to agencies responsible for facility licensing or accreditation, employee discipline, employee licensing or certification, or criminal prosecution.

(c) For purposes of any periodic audit, report, or evaluation of the performance of the P&A system, the Secretary shall not require the P&A system to disclose the identity, or any other personally identifiable information, of any individual requesting assistance under a program. This requirement does not restrict access by the Department or other authorized Federal or State officials to client records or other records of the P&A system when deemed necessary for audit purposes and for monitoring P&A system compliance with applicable Federal or State laws and regulations. The purpose of obtaining such information is solely to determine that P&A systems are spending their grant funds awarded under the Act on serving individuals with mental illness. Officials that have access to such information must keep it confidential to the maximum extent permitted by law and regulations. If photostatic copies of materials are provided, then the destruction of such evidence is required once such reviews have been completed.

(d) Subject to the restrictions and procedures set out in this section, implementing section 106 (a) and (b) of the Act (42 U.S.C. 10806 (a) and (b)), this part does not limit access by a legal guardian, conservator, or other legal representative of an individual with mental illness, unless prohibited by State or Federal law, court order or the attorney-client privilege.

§ 51.46 Disclosing information obtained from a provider of mental health services.

(a) Except as provided in paragraph (b) of this section, if a P&A system has access to records pursuant to section 105(a)(4) of the Act (42 U.S.C. 10805(a)(4)) which, under Federal or State law, are required to be maintained in a confidential manner by a provider of mental health services, it may not disclose information from such records to the individual who is the subject of the information if the mental health professional responsible for supervising the provision of mental health services to that individual has given the P&A system a written determination that disclosure of such information to the individual would be detrimental to the individual's health. The provider shall be responsible for giving any such written determination to the P&A system at the same time as access to the records containing the information is granted.

(b)(1) If the disclosure of information has been denied under paragraph (a) of this section to an individual, the following individuals or the P&A system may select another mental health professional to review the information and to determine if disclosure of the information would be detrimental to the individual's health:

- (i) Such individual;
- (ii) The legal guardian, conservator or other legal representative of the individual; or
- (iii) An eligible P&A system, acting on behalf of an individual:

(A) Whose legal guardian is the State; or

(B) Whose legal guardian, conservator, or other legal representative has not, within a reasonable time after the denial of access to information under paragraph (a), selected a mental health professional to review the information.

(2) If such mental health professional determines, based on professional judgment, that disclosure of the information would not be detrimental to the health of the individual, the P&A system may disclose such information to the individual.

(c) The restriction in paragraph (b) of this section does not affect the P&A system's access to the records.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 433

[MB-113-F]

RIN: 0938-AI30

Medicaid Program; Limitation on Provider-Related Donations and Health Care-Related Taxes; Revision of Waiver Criteria for Tax Programs Based Exclusively on Regional Variations; Correction

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

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to the final regulations that were published in the **Federal Register** on August 13, 1993 (58 FR 43156). These regulations revised the Medicaid regulations relating to limitations on federal financial participation (FFP) in State medical assistance expenditures when States receive funds from provider-related donations and revenues generated by certain health care-related taxes.

EFFECTIVE DATE: September 13, 1993.

FOR FURTHER INFORMATION CONTACT: Jim Frizzera, (410) 786-9535.

SUPPLEMENTARY INFORMATION: On August 13, 1993, we published final regulations that further implemented statutory provisions that limit the amount of Federal financial participation (FFP) available for medical assistance expenditures in a fiscal year when States receive funds donated from providers and revenues generated by certain health care related taxes. The August 13, 1993 final rule amended on interim final rule that was published in the **Federal Register** on November 24, 1992 that established in regulations the statutory limitations.

In general, the statute specified the types of health care related taxes that a State is permitted to receive without a reduction in FFP. Such taxes are broad-based taxes that apply in a uniform manner to all health care providers in a class, and that do not hold providers harmless for their tax costs. If, however, a State tax is not broad-based and uniform, a State may submit a waiver application to us requesting that we