Original: 2134

A Program of Catholic Social Services

THE COURT ADVOCATE PROGRAM

of Luzerne County

September 30, 2002

John R. McGinley, Jr., Esq., Chairman
Independent Regulatory Review Committee
333 Market Street 14th Floor
Harrisburg, PA. 17101

Dear Mr. McGinley:

The purpose of this letter is to request on behalf of Catholic Social Services, a licensed Outpatient Drug/Alcohol Provider in Luzerne, Wyoming and Pike Counties, that the Independent Regulatory Review Commission disapprove Chapter 715 Standards for Narcotic Treatment Programs as submitted by the Department of Health.

It is important that Catholic Social Services supports the need for new methadone regulations; however, we oppose the adoption of Chapter 715 as recently published. We believe that the regulations as submitted are unreasonable, costly to the Commonwealth and are not in the best interest of public health, safety, and welfare of Pennsylvania citizens.

With her rise of Heroin abuse in our area, the value of methadone services is unquestionably clear. In consideration of scant resources available for such services, every effort should be made to promote service delivery, not encapsulate it as the regulations propose.

We request that IRRC disapprove the regulations as submitted and that the Department of Health be asked to revise several items after taking into account the concerns of those most knowledgeable in the field as well a that which is consistent with most other states, with accreditation agencies, and with the recommendation of national experts.

Sincerely,

Carol Nicholas, M.A.
Project Director

aym

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Council on Chemical Abuse

Concilio de Abuso de Sustancias Químicas

Orginal: 2134

September 20, 2002

Mr. Robert Nyce, Executive Director
IRRC
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce:

This serves as a response to the proposed amendments to treatment standards for the approval of narcotic addiction treatment programs. While the majority of the new standards appear to be appropriate, there are three areas on which we would like to comment and make suggestions. These areas are specific to the psychotherapy services (section 715.19), the psychosocial staffing requirements (section 715.8) and urine testing (section 715.14).

Our comment to section 715.19 is not related to the amount of psychotherapy required for clients in treatment less than two years, but more so toward the requirements for clients in treatment beyond two years. It is not unusual for a client to be involved in Methadone maintenance for well beyond two years. In many of these instances the client is stable and uses Methadone as a maintenance medication (similar to a diabetic using insulin) and is not in need of psychotherapy services. To mandate such services could cause unnecessary hardship on the client, both in time and money, for services he/she does not need. Our suggestion would be to not require through regulation one hour of psychotherapy services for those in services beyond two years but, instead, leaving this clinical decision to the program's Medical Director. This would allow for a more clinically based offering of counseling services.

Additionally, the narcotics addictions treatment program standards would need to comply with section 704.12 regarding the full-time equivalent (FTE) maximum client/staff and client/counselor ratios. We believe that, while these ratios are appropriate for clients in a more acute treatment setting, these ratios are not necessary for maintenance-type programs. As noted above, there are typically many long-term clients (over two years) in a maintenance program who may no longer require regularly a scheduled counseling regimen. These clients are included in the client/counselor ratio even through they require very little monitoring by a

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counselor. While these long-term clients require monitoring, we believe they do not need the oversight of a qualified therapist. Therefore, we suggest that clients who, after a two-year period, no longer need regular counseling either not be counted towards the client/counselor ratio or be counted as some percentage of a client.

Finally, we believe that clients in the early stages of narcotic addiction treatment should be required to undergo more frequent urine drug testing than one per month. Our belief is that narcotic-dependent clients in the early stages of treatment need to be monitored closely for relapse into drug and alcohol use. Unchecked relapse will result in poor client treatment retentions and unsatisfactory long-term outcomes. We suggest that urine testing for the first two years of narcotic addiction treatment should be a minimum of once per week.

The opportunity to comment on the proposed changes in these treatment standards is appreciated. Please feel free to contact me for further clarification regarding any of the above comments.

Sincerely,

George J. Vogel, Jr.
Executive Director

cc: Representative Sheila Miller
Glenn Cooper, New Directions Treatment Program

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Council on Chemical Abuse
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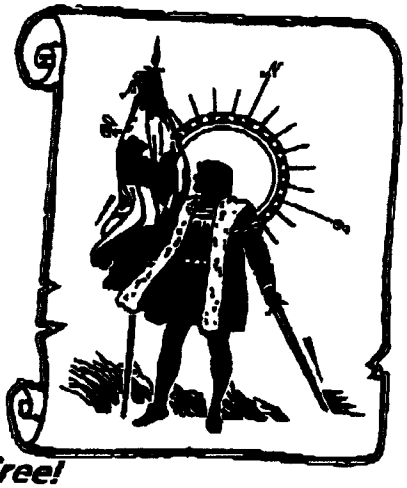
FAX COVER SHEET

Date: 9/23	**No. of Pages, including cover:**
To: Robert Nyce	**From:** George Vogel
Agency: IRRC	
Fax Number: 717-783-2664	**Fax Number: 610-376-8423**
Comments:	

If you encounter any difficulties during transmission, please call 610-376-8669.

Columbus Day • October 14, 2002



A FAX WITH FACTS

- Purchase and public possession of alcohol by people under age 21 is illegal in all 50 states.
- Approximately 2/3 of teenagers who drink report that they can buy their own alcoholic beverages.

The Choice For Me.... Drug-Free!

Original: 2134

Pennsylvania Association of Methadone Providers

September 19, 2002

Dear Commissioners and Staff,

These comments are the response to proposed, final form Chapter 715 methadone regulations by the Pennsylvania Association of Methadone Providers which represents the providers of outpatient methadone treatment services for the vast majority of the state's 8,000+ methadone patients. Our Association believes that this entire process has not been handled well by the department in terms of communication with the regulated community and having regulation reflect the expert opinion residing in the regulated community. Methadone treatment providers in Pennsylvania are weary of having to provide methadone treatment services in an extremist regulatory environment. That the Chapter 715 proposal is extreme can be readily seen by comparing many of its key proposals with the position of other states (see enclosed) and by comparing regulation of methadone services with that of other health services. The current regulatory environment and that implied by Chapter 715 does not adequately account for the fiscal impact of regulations and imposes an extremely prescriptive oversight function. This has had the result of inhibiting the expansion of services to those in need and in driving patients out of treatment who then relapse to heroin with all its attendant difficulties. There is a major problem with access to this important service in the Commonwealth, much of which problem is attributable to regulations that are out of balance with available funds.

There has been very little communication on the subject of these regulations between our Association and the department since they were published as "proposed" two years ago and certainly nothing that could be considered negotiation. This was not due to lack of interest on our part. The "stakeholders" meetings that preceded the original publication were not effective in terms of attendees, interpretation of the discussion, and the large amount of language added later that was never subjected to the process. While we do support the need for development of new methadone regulations, we oppose the adoption of Chapter 715 as recently published.

We request that the Commission disapprove the following sections of the proposal:

- 715.7 Dispensing or administering staffing

  (a)(1) - The language specifying one full-time equivalent dispensing staff for 200 patients is excessively restrictive and should instead reference 300 patients. Neither accreditation standards (e.g., JACHO, CARF) nor most other states specify any maximum number (see enclosed). Further, the department has presented no evidence to support this requirement as was requested. We believe that department personnel involved in writing these standards have neither medical qualifications nor experience in operating methadone treatment facilities which would give them expertise in this subject area.

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(b) - We object to new language specifying a 15 minute time period for dosing. This requirement is excessively restrictive and has not been subject to normal rule-making comment procedures. We are unaware of any other state that has any time restriction. While we don't believe a time limit is appropriate, if there was a limit it should be "on average", not a maximum in order to account for unusual situations.

- 715.8 Psychosocial staffing

We believe the counselor to patient ratio of 35:1 is damaging to programs with many long-term stabilized patients on reduced counseling schedules. It puts programs in the position of either being unable to recover counselor costs or of forcing patients to get counseling services they don't need (costs which drive patients out of treatment prematurely). The 35:1 requirement is beyond what is in "best practices" accreditation standards and what most other states with a substantial methadone patient population require (see enclosed). Likewise, FDA/NIDA federal guidance has been a 50:1 ratio (see enclosed). Chapter 704 regulations on this subject are simply not appropriate for methadone treatment where fully rehabilitated patients remain in treatment often for years at a time. We advocate a ratio of 50:1 if a ratio must be employed. Most states have no ratio and with good reason (see comments of Mark Parrino, President of AATOD, enclosed). We would suggest using counselor contact hours or other means of ensuring that counselors are not overextended. For example, a clinic with a lot of long-term patients could choose meeting either a counselor/patient ratio or show that none of their counselors spends more than 60% of their time in face-to-face counseling.

- 715.19 Psychotherapy services

This entire section specifies that all patients in treatment for a particular length of time receive what are quantitatively the same counseling services. As is noted by Mark Parrino, President of AATOD, such requirement is inappropriate and wasteful and should not be required unless the state is willing to guarantee payment for services (see enclosed). There is an acute lack of resources in regard to methadone treatment generally. Therefore, every dollar must be spent with utmost care and no resources can be wasted as is the case with the department's regulatory approach. The regulatory language should exempt from any counseling requirement those patients who have shown evidence of being rehabilitated and free of illicit drugs for an extended period of time as certified by the medical director. It is a common scenario where a patient left treatment voluntarily and later returned because of a recent or impending relapse. Such patients often have an ongoing need for medication but have already had years of counseling and should not have to pay for maximum counseling services which they don't need and can't afford.

- 715.25 Prohibition of medication units

  The department, in its comments response, misstates the nature of medication units. It is patently untrue that persons medicated at medication units do not receive counseling or other comprehensive services provided at traditional program settings. The federal definition states that such are part of a narcotic treatment program and the federal definition of narcotic program requires comprehensive services. The department simply objects to physically separating the medication function from the other functions. The department's comments are, thus, misleading at best. In a large, mostly rural state with few methadone programs, medication units are essential. Many persons cannot drive 100 or 150 miles round trip daily and doing so prevents employment and other patient advancements. Coming to the clinic site once per week for counseling and other services while getting daily medication close to home is much more feasible. The current prohibition also is costing the Commonwealth hundreds of thousands of dollars per year in mileage payments to Medical Assistance patients. If the department is concerned about such units being "hundreds of miles" distant, we do not object to reasonable restrictions rather than outright prohibition.

We are not specifically asking the Commission to disapprove the additional sections indicated below but note that our membership believes that the issues are not addressed appropriately in the proposal:

- 701.1 Definitions; Narcotic treatment physician

  The definition would require the same credentials for this position as for the medical director as stipulated in 715.6 (a)(1). This is completely inappropriate and would result in major recruitment problems for programs. It would disqualify most psychiatrists, AIDS specialists, and others programs now can count toward meeting physician hour requirements. The language of 715.6 (a)(1) has the appearance of setting a special qualifications requirement for medical directors which the language in 701.1 actually applies to all physicians.

- 715.1 General provisions

  (a.) - In the interval between proposed and final rule-making, the federal government has identified buprenorphine as an agent used for maintenance of narcotic addicts which the states by law may not regulate without specific authorizing legislation. (Final FDA approval expected in November, 2002). There may be other such federal restrictions in the future. This paragraph should be modified to recognize this development.

- 715.4 Denial, revocation, or suspension of approval

  (a.) - The only appeal mechanism under the proposal is if the department takes legal action to revoke or suspend licensure. It is essential that programs have

recourse short of provoking such action in order to question an inappropriate departmental order or citation. The existing regulations do provide for an appeals mechanism but, unfortunately, to the Governor's Council which no longer exists. An appeals mechanism should include an attorney, a medical professional, and department staff beyond the licensing division. Including a service provider and/or an SCA representative would also be good. It's important to have a medical person on an appeals committee because no one in the licensing division has any qualifications in the medical field.

- 715.5 Patient Capacity

In regulating patient capacity, the department bestows on itself an extraordinary power over what are private sector health care services. Most states do not regulate patient census. In the event that such extraordinary power is granted, it is essential that it be an absolutely open, objective process with specific benchmarks and an appeals mechanism. The language added in the final form version does not meet that standard. Rather, it simply lists topics that will be considered. In the past, the department has abused this power in regard to regulating capacity. We also question the new language to state "decrease" as well as to limit increases. If a program is deficient, there are ample remedies in place to deal with such noncompliances and this is a new provision not permitted at this stage of the rule-making process.

- 715.6 Physician staffing

(d) - While concession made on the issue of nurse practitioner hours help programs which use them, other programs do not use them. The proposed 1:10 ratio is excessive, unnecessary, and inconsistent with the regulation of methadone in other states (see enclosed). It's important to remember that the nature of methadone treatment has changed in recent years such that stabilized patients are remaining in treatment, thus reducing the percentage of patients who need more intensive services. We agree that issues of hepatitis, AIDS, and so on are important issues for patients in general but they are not important in terms of how many physician hours are required for the regulated activities at issue. Certainly, the department has not polled medical directors on this issue nor has the department given the evidence as to need for this ratio as was requested in comments.

(e) - The language on the use of nurse practitioners (CRNP) and physician's assistants (PA) would be better written such as to permit them to perform all functions not legally prohibited (rather than functions which are "authorized"). Many functions in methadone treatment, such as determining a one year history, are specialized and are not specifically referenced in authorizing legislation.

- 715.9 Intake

  (a)(4) - We believe the nature of heroin and opiate addiction has changed significantly in recent years such that language should specify that the department will provide a physician to discuss exceptions to the 1 year requirement with program medical directors. In the past, such discussions have been limited to licensing's staff which is exclusively non-medical.

- 715.12 Informed patient consent

  We object to the term "addictive" in "(2)" which would have been more appropriately termed "physical dependency - producing" medications. Also, the term "may" should replace "will" in subsection (5) if new language is permitted.

- 715.14 Urine testing

  Language should not specify which drugs will be the focus of testing and, if it does, should not include amphetamines or barbiturates. These are not commonly used drugs by methadone patients in Pennsylvania. Further, provision should be made for testing fluids other than urine since such tests are now coming into use (see enclosed).

- 715.16 Take-home privileges

  (c) - We would favor the more liberal approach of the new federal take-home regulations. Such an approach has been adopted by a number of states including ones contiguous to Pennsylvania (see enclosed). This is also the approach recommended for Pennsylvania by Mark Parrino, President of AATOD, the national methadone treatment organization (see enclosed). It is essential that rehabilitated patients who cannot successfully withdraw from methadone treatment be able to live a reasonably normal life or they will leave treatment. It is thus an important clinical issue, not merely an issue of convenience. Experts believe that means a take-home schedule up to and including 30 per month for fully rehabilitated patients. Regulatory people commonly exaggerate the attendant problem of diversion of methadone. The vast majority of street methadone is diverted pain medication, not methadone from addiction treatment clinics. Certainly, there is no basis in restricting methadone from a maintenance clinic's rehabilitated patients to a greater extent than methadone prescribed for pain, than Valium or other prescribed benzodiazepines, Oxycontin, Percocet, or all of the other prescription medication which is sometimes diverted. Persons receiving these medications do not have to return to take them in their physician's office daily. As with other medication, the problem of diversion has to be balanced with clinical considerations. There is no evidence that states which have liberalized their take-home schedules have had a significant increase in diversion.

- 715.21 Patient termination

  (1) - Termination of patient treatment for reason on nonpayment should be included on the list of reasons in this subsection. It is recognized both by accreditation agencies (see CARF standards enclosed) and by national experts (see letter of Mark Parrino, enclosed) as a legitimate reason for termination of treatment. The department themselves already permit termination for nonpayment where the patient refuses to make payment but not inability to pay. We would suggest that it is in many cases impossible to make that distinction. There are other forms of treatment to which nonpaying patients can be referred and certainly many persons are successfully treated in drug-free programs. Providers would very much like to operate in an environment where the government would guarantee payment for services rendered and the survival of programs but, unfortunately, that is not the environment that exists at present. There is no other outpatient medical service which is expected to be provided at no cost over potentially a years-long period where patients can simply stop paying fees without being discharged. Likewise, it is a violation of Medical Assistance regulations to bill that department for services provided free or at less cost to others.

We suggest that the department be required to submit a revised version of Chapter 715 after taking into account the legitimate concerns of those most knowledgeable in the field and which is consistent with most other states, with accreditation agencies, and with recommendation of national experts. Thank you for the opportunity to comment on these proposed regulations.

Sincerely,

Glen J. Cooper
President

Comparison of PA proposed Chapter 715 with federal standards, with all other states having 6,000+ patients, with contiguous states, and with accreditation standards

	Physician Ratio	Nurse Ratio	Counselor Ratio	Medication Units	Take-Home Doses (Max)	Minimum Counseling	Termination Non-Payment	Regulate Capacity	Max Dose Time
PA proposed	**10:1**	**200:1**	**35:1**	**No**	**6/week**	**2.5 hrs./mo.**	**No**	**Yes**	**Yes**
CARF accreditation	None	None	None	Yes	30/mo.	None	Yes	N/A	No
Federal Regulations	None	None	None	Yes	30/mo.	None	Yes	No	No
Ohio	None	None	None	No	13/two weeks	None	?	No	?
Maryland	None	None	35:1	Yes	30/mo.	None	Yes	No	No
Delaware	None	None	None	Yes	30/mo.	None	Yes	No	No
New Jersey	1 f.t./300 draft stds. will	150:1 soon eliminate	50:1 ratios	No	30/mo.	Phased (see notes)	Yes	No	No
New York	1 f.t./300	150:1	50:1	Yes	30/mo.	None	Yes	Yes	No
Connecticut	None	None	None	Yes	30/mo.	1.0 hr/mo.	Yes	No	?
California	None	None	None	Yes	30/mo.	1.0 hr./mo	Yes	Yes	?
Texas	None	None	50:1	Yes	30/mo.	None	Yes	Yes	No
Florida	None	None	None	Yes	30/mo.	Phased	Yes	Yes	?
Illinois	None	None	50:1	Yes	30/mo.	1 contact/mo	Yes	No	?
Massachusetts	None	None	None	Yes	30/mo.	None	Yes	No	No

Notes: 1) Minimum counseling shown is for first 2 years; some states have complex phased system that takes into account how the patient is progressing as the requirement; 2) CARF is a private sector company (similar to JACHO) and enforces standards for methadone treatment which programs must meet; 3) Most responses were received from regulatory agencies but, where necessary, were determined via interview with programs; 4) a couple of states restrict termination for nonpayment to for-profit programs or to nonsubsidized patients; 5) question marks in the grid indicate an ambiguous response or nonresponse to the survey; 6) PA proposal would allow 13 take-homes in a 2-week period but only for disabled patients; 6) Responses to issue of medication units refers to prohibited by regulation or not; 7) Take-home doses where patient comes on-site once per month are shown as 30/mo. even though some states operate on a 28-day "month"; 8) Physician and nurse ratio are patients per hour and per full-time person respectively. Counselor is patients per full-time counselor; 9) Florida uses contact hours formula for counselor load which in practice is much less restrictive than PA proposal.

Standards Manual

Opioid Treatment Program Accreditation

19.b. Voluntary withdrawal from methadone/LAAM therapy, as distinct from involuntary withdrawal and administrative withdrawal and other types of withdrawal, is initiated only when desired by the person served, in partnership with the physician.

CARF Accreditation "Best Practices" Standards

20. When medical withdrawal is conducted against medical advice:

The program should document:

(1) Efforts taken by program staff members to avoid discharge.

(2) Reasons the person served is seeking discharge.

b. The record of the person served must remain active for at least 30 days.

Interpretive Guidelines

20. While every effort should be made to retain persons in treatment, individuals have the right to leave treatment when they choose to do so.

21. Prior to the beginning of administrative withdrawal:

a. Efforts are documented regarding referral or transfer of the person served to a suitable, alternative treatment program.

b. Due process procedures are implemented with provisions for appeals or grievances.

Interpretive Guidelines

21. Ongoing multidrug abuse is not, in itself, a reason for discharge unless the person served refuses recommended and more intensive levels of treatment. Involuntary administrative withdrawal should be a decision when all other efforts at retention have failed. This type of withdrawal is typically brief and often does not extend beyond thirty days. Reasons for administrative withdrawal may include non-payment of fees or conduct or behavior considered to have an adverse effect on the program, staff members, or person served such as:

Note →

- Violence or threat of violence.
- Dealing drugs.
- Repeated loitering.

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September 9, 2002

Dear Mr. Cooper,

In response to your request, I'm writing to confirm our conversation to the effect that a few years ago our methadone treatment program relocated to New Jersey from Pennsylvania due entirely on regulatory issues. Pennsylvania's regulations and the manner in which they were interpreted made it very difficult to provide quality services at a cost our patients could afford. New Jersey has a more reasonable approach in allowing patient services and staffing to be clinically driven rather than using ratios and prescribed amount of counseling. Likewise, New Jersey's take-home policy makes it more realistic for patients to remain in treatment. Put simply, patients get better treatment in New Jersey due to treatment being outcome based. New Jersey allows our doctors to practice medicine. Our Performance Improvement meeting indicators have shown an increase in stable (testing positive for methadone only) patients after leaving Pennsylvania. Our company is pleased with the results of our relocation across the border and would not consider returning to Pennsylvania unless there is a regulatory reform in your state. I hope this letter will help in providing better treatment to all the 304.00 patients in your state.

Gary D. Gavornik
Director

Jointly by FDA + NIDA

When a person is readmitted to a program, it is recommended that the decision determining the appropriate laboratory tests to be conducted be based on the intervening medical history and a physical examination.

Admission Evaluation

A patient's history should include information relating to his or her psychosocial, economic, and family background, and any other information deemed necessary by the program that is relevant to the application or that may be helpful in assessing the resources, e.g., psychological, economic, educational, and vocational strengths and weaknesses, that a patient brings to the treatment setting. Each program should establish its own methods for measuring those strengths and weaknesses to assess the severity of the patient's problem, establish realistic treatment goals, and develop an appropriate treatment plan to achieve these goals. Such assessments should be made on admission or as soon as the patient is stable enough for appropriate interviewing. Treatment plans should reflect individualization geared to the patient's needs.

Initial Treatment Plan

The short-term goals contained in the initial treatment plan should be designed to expect completion within a finite time period, e.g., 90 to 180 days.

The information contained in the initial treatment plan should be in sufficient detail to demonstrate that each patient has been assessed and that the services provided are based on the patient assessment findings and the available program and community services.

Patients need varying degrees of treatment and rehabilitative services which are often dependent on or limited by a number of variables, e.g., patient resources, available program, and community services. It is not the intent of 21 CFR 291.505 or this guidance document to prescribe a particular treatment and rehabilitative service or the frequency at which a service should be offered.

Periodic Treatment Plan Evaluation

Changes made to a treatment plan should be fully explained to the patient.

Pregnant Patients

If a pregnant patient refuses direct prenatal services or appropriate referral for prenatal services, the treating program physician should consider using informed consent procedures, i.e., to have the patient acknowledge in writing that she had the opportunity for this treatment but refuses it.

Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if continued methadone treatment is deemed necessary. Detoxification treatment is not recommended for a pregnant patient.

Staffing Level

Programs that are not treating a large number of patients in maintenance treatment with a once weekly clinic visit schedule should maintain a staffing level ratio of at least 1 counselor to 50 patients.

Initial Dose

The initial dose of methadone should be given in an amount considered sufficient to control or mitigate abstinence symptoms concomitant to withdrawal of narcotic drugs. Currently, there is no absolutely reliable method available to determine narcotic tolerance levels. Thus, determination of the optimum initial dose is made on a case-by-case basis. Methadone dosages that are lower than the patient's current level of narcotic tolerance may result in the patient's experiencing withdrawal symptoms. Dosages sufficiently greater than the current level of narcotic tolerance can result in central nervous system depression, coma, and death. Therefore, it is important that the initial dose be adjusted individually to the narcotic tolerance of the patient. If the patient has been a heavy user of heroin up to the day of admission, he or she may require an initial dose of 15 to 30 milligrams with additional smaller increments 4 to 8 hours later. It is recommended practice that if the patient enters treatment with little or no narcotic tolerance (e.g., recently released from jail or using poor quality heroin), the initial dose be one-half these quantities. If there is any doubt, the smaller dose should be used initially and the patient kept under observation; if the symptoms of abstinence are distressing, an additional 5- to 10-milligram dose should be administered as needed. Subsequently, the dosage should be adjusted individually as tolerated and required. The stabilization dose frequently, but not necessarily, is higher than

POSITION OF THE AMERICAN ASSOCIATION FOR THE TREATMENT OF OPIOD DEPENDENCE (AATOD) ON THE SUBJECT OF PROPOSED CHAPTER 715 REGULATIONS; EXCERPTS FROM THE LETTER OF MARK PARRINO, AATOD PRESIDENT, DATED JUNE 12, 2002:

Staffing Pattern Requirements

"The new federal accreditation standards are general in nature and are designed to provide flexibility in allowing the program to determine the best methods of developing staffing patterns to meet the needs of its patient population.

When the first TIP was written (State Methadone Treatment Guidelines), we consciously avoided any reference to specific staffing pattern recommendations. We knew that patient characteristics would differ from program to program and state to state...

The true value of having any state regulation specifically reference the number of hours for a particular clinician is if there is some contemplation that funds will be provided to ensure that such services can be realistically provided. If there is a true interest in ensuring that patient needs are met through a particular staffing pattern, whether that includes a physician or primary care counselor, there has to be some justification for making any specific staff member/patient ratio."

Patient Counseling Requirements

"I understand the intent of the proposed rule-making, stipulating that 'an average of 2.5 hours of psychotherapy per month during the patient's first two years' be provided to each patient. The problem with such specificity is that not all patients will require such services throughout the first two years in treatment. They might well require such services during the first 180 days, however, it truly is dependant on the individual patient's response to care.

The same issue comes to surface with the requirement of providing 'each patient at least one hour per month of group or individual psychotherapy after two years'. Once again, this depends on the patient. One can just as easily argue that some patients will require intensive services after two years in treatment. The length of time in treatment is not the critical issue. The most significant matter is how well the patient is responding to treatment during the therapeutic process...

Putting the issues of cost aside for the moment, I recommend that this section be reviewed purely based on the different clinical needs of patients during the treatment process. Some general standard of care can be established if the proposed rule-making must include some specific reference to staffing/patient ratios, then there must be some general consideration given to the costing-out of these services. The point here is once the standards have nothing to do with the clinical needs of the patient, there has to be some relationship to cost, especially if ratio is determined."

Take-Home Medication

"I would encourage the Pennsylvania Department of Health to reevaluate the requirements for 'take-home'. Given the stated intent of having 'state methadone regulations to more closely align with the federal regulations', a reasonable recommendation would be to have the state adopt the recommended federal take-home standards. A number of states have already made this decision while some others have promulgated slight variations.

In order to be consistent with the general purpose of the standards, with some degree of federal alignment as stated above, this section should be appropriately modified."

AATOD
American Association for the Treatment of Opioid Dependence, Inc.
A Tax Exempt Corporation

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Email: AmerMeth@aol.com
www.AATOD.org

June 12, 2002

Glen J. Cooper
President
Pennsylvania Association of Methadone Providers
1810 Steelstone Rd.
Allentown, PA 18109

Dear Glen:

I am responding to your prior correspondence concerning the Pennsylvania Department of Health's proposed rule-making for methadone treatment programs. Obviously, the implementation of any statewide regulatory requirements for methadone treatment standards should be aligned with the newly promulgated CSAT accreditation standards for OTPs.

It is also understood that state officials and treatment providers will take a different perspective in responding to the promulgation of any new standard. State regulators typically take the view that standards need to be as clearly defined as possible, ensuring that the public interest, including patients, is properly protected. There is a desire to ensure that good-quality standards of care are being uniformly delivered to a comorbid patient population in a therapeutic treatment environment.

Generally, the promulgation of such statewide standards does not take into account the cost of providing such comprehensive care. One would certainly hope that there would be consideration given to such issues. Illustratively, a state agency could require treatment providers to provide a depth of service that is prohibitively expensive. If this should occur, programs would not be able to survive in meeting the promulgated standards. No one benefits from excessively burdensome standards of care.

On the other hand, providers need to come to terms with what is known about the provision of good-quality comprehensive treatment standards, responding to the needs of a comorbid patient population. Our patient population has changed dramatically over the years, with greater psychiatric comorbidity, increased HIV infection rates, significantly increased Hepatitis C infection rates and a series of other challenges to the treatment system.

Our Association has supported the use of clinically effective standards, rendered in a therapeutic milieu, since the publication of the 1993 State Methadone Treatment Guidelines. Our Association's ethical canon is equally clear on the need to respond to the needs of the patient.

Establishing standards for opioid treatment programs is an extremely complex process but one that does have some finite solutions. It is my hope that the following comments will be of value to you and our provider colleagues in Pennsylvania as these standards are being considered for promulgation.

General Commentary

It is important to note that the proposed amendment to treatment standards for the approval of "narcotic addiction treatment programs" was disseminated to the Pennsylvania methadone providers during August, 2000, in advance of the federal government's accreditation standards, which were implemented on May 18, 2001. Accordingly, language and other references need to be changed in order to be in "alignment" with the newly promulgated federal standards under the oversight authority of SAMHSA/CSAT.

It is encouraging to note that the purpose of the proposed rule-making references "the need...to amend state methadone regulations to more closely align with the federal regulations, as well as incorporate current treatment practices for narcotic addicts." I would recommend that language reflect more current and therapeutic reference points, such as a removal of the term "narcotic addicts", which is pejorative, and replace it with "opioid dependent individuals". This may seem like a small point when measured against the proposed rule-making, but it is essential just the same to reflect the intent of the regulations.

The following specific points should be taken into account in responding to the proposed rule-making authority.

1. All references to the Food & Drug Administration should be deleted and replaced with CSAT, since they have the regulatory oversight authority for accreditation under the aegis of SAMHSA/DHHS. In addition, all references to the previous federal citations should be changed to conform to the new federal standards.

2. The term "opioid treatment program" should replace all references to "narcotic treatment programs", which is currently in the Pennsylvania proposed rule-making.

3. The proposed standards have an internal conflict in referring to patients and clients. My recommendation would be to delete the term "client" completely, exclusively utilizing the term "patient" throughout the rule-making document.

4. The previously cited federal standard, establishing a distinction between long-term detoxification (180 days or less) and methadone maintenance treatment (181 days or more), should be deleted; the new federal standards no longer make any such distinction.

5. In addition to the removal of this distinction, I am recommending that the proposed rule-making amend the following statement. "The ultimate goal of maintenance is to assist the client (patient) in permanently discontinuing the use of dependency-producing substances." This could be misinterpreted as indicating that the ultimate goal of methadone maintenance treatment is to limit the patient's access to any maintenance medication. After all, one can argue that methadone as a medication is a "dependency-producing substance". I understand the intent of the language, however, it might be better to have a general statement about the therapeutic use of methadone as long as a patient needs access to such care as the patient eliminates his/her dependence on illicit substances. The other alternative is to eliminate the statement completely.

Administrative Issues

Staffing Pattern Requirements

It is understood from the inception that federal and state standards tend to differ on the specifics of staffing pattern requirements. The new federal accreditation standards are general in nature and are designed to provide flexibility in allowing the program to determine the best methods of developing staffing patterns to meet the needs of its patient population.

When the first TIP was written (State Methadone Treatment Guidelines), we consciously avoided any reference to specific staffing pattern recommendations. We knew that patient characteristics would differ from program to program and state to state. There were some general recommendations made and the newly configured methadone specific TIP (CSAT initiative to combine four existing methadone TIPs into one encyclopedic reference) will continue to provide some general direction.

The first TIP anticipated the kind of issue that the Institute Of Medicine would explore in its 1995 review of federal regulation of methadone treatment. Ultimately, the NIH/NIDA consensus development panel also recommended the promulgation of accreditation standards, reducing overly burdensome regulatory standards, which were seen as counterproductive to meeting patient needs. The idea was to provide flexibility in meeting the specific needs of patients as they improved through the treatment process.

The idea was to ensure that patients would have greater access to more intensive therapeutic treatment services during the earliest part of treatment (1 – 180 days) as opposed to continuing such intensive services throughout the treatment process once the patient had achieved some degree of stability, both medically and psychologically.

There is a vast middle-ground of patient needs once they have achieved this early stability and before the patient reaches a period of more profound stability, as evidenced by 36 months of ongoing clinical care showing no signs of alcohol or other drug use. I generally reference the "medical maintenance" paradigm as this latter stage of treatment. As stated, the middle stages of treatment can take a very long time for certain patients. This has been referenced in the literature, especially in the Moolchan/Hoffman "Phases of Treatment" articles.

While the issues of cost naturally enter into this discussion, especially as relates to the number of physician hours relative to total patient population and the number of primary care counselors in ratio to a specific patient population, I am referencing clinical care standards at this point.

The true value of having any state regulation specifically reference the number of hours for a particular clinician is if there is some contemplation that funds will be provided to ensure that such services can be realistically provided. If there is a true interest in ensuring that patient needs are met through a particular staffing pattern, whether that includes a physician or primary care counselor, there has to be some justification for making any specific staff member/patient ratio.

Obviously, the proposed rule-making does provide some flexibility as relates to physician services and the use of other licensed/certified health care professionals, fulfilling functions within opioid treatment programs and some portion of the specific physician to patient ratio.

The proposed rule-making on dispensing staffing requirements present a more practical example. It provides a differentiation between the number of dispensing staff members that might be required to treat a specific patient population depending on the use of an automated dispensing system or a manual dispensing system. Given my experience in working in methadone treatment programs and in reviewing other state standards, this particular staffing to patient ratio makes some sense, however, it is also a function of available operating hours of the clinic.

The reference to "psychotherapy services" should probably be changed to "counseling services", since most methadone treatment programs really do not provide access to psychotherapy for their patients. "Counseling services" generally captures the true nature of what occurs within the opioid treatment program.

I understand the intent of the proposed rule-making, stipulating that "an average of 2.5 hours of psychotherapy per month during the patient's first two years" be provided to each patient. The problem with such specificity is that not all patients will require such services throughout the first two years in treatment. They might well require such services during the first 180 days, however, it truly is dependent on the individual patient's response to care.

The same issue comes to surface with the requirement of providing "each patient at least one hour per month of group or individual psychotherapy after two years". Once again, this depends on the patient. One can just as easily argue that some patients will require intensive services after two years in treatment. The length of time in treatment is not the critical issue. The most significant matter is how well the patient is responding to treatment during the therapeutic process. If a patient is medically stable on their dose of methadone and has been successful in not using/abusing alcohol and other drugs, is working or in school, is not being treated for any psychiatric comorbidity, and such stability is achieved within a one-year period of time, one will be hard pressed to justify the continued exposure to more intensive counseling services.

Putting the issues of cost aside for the moment, I recommend that this section be reviewed purely based on the different clinical needs of patients during the treatment process. Some general standard of care can be established if the proposed rule-making must include some specific reference to staffing/patient ratios, then there must be some general consideration given to the costing-out of these services. The point here is once the standards have nothing to do with the clinical needs of the patient, there has to be some relationship to cost, especially if an arbitrary ratio is determined.

Recognizing that treatment providers and state regulatory oversight bodies might not agree in determining staffing pattern requirements, exceptions should be considered on a program-by-program basis, responding to patient characteristics in a particular clinical setting. In such cases, the state regulatory body would outline the "rules of engagement" for program-by-program exceptions, which would apply to physician coverage, dispensing personnel and counseling staff.

Clinical Treatment Issues

I would encourage the Pennsylvania Department of Health to reevaluate the requirements for "take-home privileges". Given the stated intent of having "state methadone regulations to more closely align with the federal regulations", a reasonable recommendation would be to have the state adopt the recommended federal take-home standards. A number of states have already made this decision while some others have promulgated slight variations.

In order to be consistent with the general purpose of the standards, with some degree of federal alignment as stated above, this section should be appropriately modified.

I would also modify the section on "urine testing" to more accurately embrace some of the newer available technologies in toxicology testing. The federal standards reference "drug abuse testing services" without providing any specific reference to the more specific urine testing toxicology.

While I am not recommending the use of any particular drug screening test, it is recommended that the most general reference made to an effective drug treatment test versus the specific urine toxicology test.

There is a reference to treating pregnant patients with methadone dosages "maintained at the lowest effective" dose levels. Once again, there is no need to guide the providers in using lesser methadone doses. It is far better to make the statement that therapeutic doses will be administered to pregnant methadone maintained patients. The reference to the matter of "lowest effective dose" should be eliminated.

I also suggest that some reference to LAAM and cardiac conduction be presented in the proposed rule-making. It does not have to be a significant point of reference but should acknowledge the fact that LAAM can cause prolonged QTC intervals in certain patients. You already have a copy of the Association's ORLAAM guidelines and you should feel free to reference them in this regard.

I realize that there are some other issues that could come into play in reviewing the proposed standards of care. I chose to focus on what I consider to be the most significant issues that merit consideration.

I have tried to present a reasonable and balanced perspective, which may create some consternation among different parties, depending on where you sit in the decision making process. I hope that my comments have provided some guidance and please feel free to call with any additional questions.

Sincerely yours,

Mark W. Parrino, MPA
President

CooperG 060302sb

Pennsylvania Psychiatric Society

The Pennsylvania District Branch of the American Psychiatric Association

Original: 2134

[illegible] 17 AM 8:42

[illegible]

September 11, 2002

Mr. John R. McGinley, Jr., Esq., Chairman
Independent Regulatory Review Commission
333 Market Street, 14th floor
Harrisburg, PA 17101

Dear Mr. McGinley:

I am writing on behalf of Frederic Bauer, MD, who chairs our Committee on Addiction Psychiatry, to support the final rulemaking of the Department of Health regarding narcotic treatment facilities. Our understanding is that this regulation, #10-159, is scheduled for Commission action on September 26.

Dr. Bauer and his committee members, who have medical sub-specialty certification in addiction psychiatry, are pleased that the few but important reservations they had in regard to the earlier version have largely been eliminated by the Department of Health in the final document. We are particularly pleased with the overall attention paid to staffing issues and the Department's recognition of the medical complexities that are frequently present in the treatment population.

We appreciate the opportunity to comment on this regulation, and urge your support for its approval.

Sincerely yours,

Gwen Yackee Lehman

Gwen Yackee Lehman
Executive Director

Cc: Frederic Bauer, MD

Executive Director
Gwen Yackee Lehman
777 East Park Drive
P.O. Box 8820
Harrisburg, PA
17105-8820

(800) 422-2900
(717) 558-7750
FAX (717) 558-7841
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Membership Office (888) 861-1181

www.papsych.org

Original: 2134

CATHOLIC SOCIAL SERVICES

Wyoming Valley

Office

September 30, 2002

John R. McGinley, Jr., Esq., Chairman
Independent Regulatory Review Committee
333 Market Street 14th Floor
Harrisburg, PA. 17101

Dear Mr. McGinley:

The purpose of this letter is to request on behalf of Catholic Social Services, a licensed Outpatient Drug/Alcohol Provider in Luzerne, Wyoming and Pike Counties, that the Independent Regulatory Review Commission disapprove Chapter 715 Standards for Narcotic Treatment Programs as submitted by the Department of Health.

It is important that Catholic Social Services supports the need for new methadone regulations; however, we oppose the adoption of Chapter 715 as recently published. We believe that the regulations as submitted are unreasonable, costly to the Commonwealth and are not in the best interest of public health, safety, and welfare of Pennsylvania citizens.

With her rise of Heroin abuse in our area, the value of methadone services is unquestionably clear. In consideration of scant resources available for such services, every effort should be made to promote service delivery, not encapsulate it as the regulations propose.

We request that IRRC disapprove the regulations as submitted and that the Department of Health be asked to revise several items after taking into account the concerns of those most knowledgeable in the field as well a that which is consistent with most other states, with accreditation agencies, and with the recommendation of national experts.

Sincerely,

Ned Delaney, M.A.
Executive Director

aym

33 East Northampton Street, Wilkes-Barre, PA 18701-2492
(570) 822-7118 • FAX (570) 829-7781

Original: 2134

IRRC

From: Valentine, Pat [PValentine@dhs.county.allegheny.pa.us]
Sent: Tuesday, September 24, 2002 9:51 AM
To: IRRC
Subject: PROPOSED METHADONE REGULATIONS

Importance: High

Please accept the following recommendations with respect to Pennsylvania's proposed revised methadone regulations.

1. The counselor to client ratio should be 1 to 50.
2. The nurse to client ratio should be 1 to 300.
3. We recommend that the minimum counseling time per month be reduced to one (1) hour.

These recommendations are in accordance with national standards and CARF accreditation standards.

Thank you for your consideration of these recommendations.

Sincerely,

Patricia L. Valentine
Deputy Director for Behavioral Health Services
Allegheny County Department of Human Services

Original: 2134

IRRC

From: Sari Trachtenberg [Sari.Trachtenberg@mail.tju.edu]
Sent: Tuesday, September 24, 2002 8:06 AM
To: IRRC
Subject: methadone regulation changes

Dear IRRC:

I am writing to let you know of our support for the position held by PAMP with regards to the proposed changes to the Methadone Regulations. We believe that the limitations imposed by these changes will not allow us to continue to provide the services to our patients, necessary to treat them efficiently. We concur with PAMP on all the points and issues outlined in their statements to you.

Sincerely,
Sari Trachtenberg, Program Coordinator
The Narcotic Addiction Rehabilitation Program of
Thomas Jefferson University NARP

Original: 2134
IRRC

From: Garrett, Dot [Dot.Garrett@crozer.org]
Sent: Tuesday, September 24, 2002 9:09 AM
To: IRRC
Cc: Zuggi, Sandra
Subject: Chpt715 regulations

Glen ---

Crozer Chester Medical Center - Methadone Program supports PAMP's position that programs need more latitude for clinical judgement and to be more like other states and compatible with the federal approach.

Thanks for your attention to these issues.

Sandra Zuggi, RN,C, CAC
Program Coordinator
9/24/02

OriginL: 2134

National Alliance of Methadone Advocates
State of Pennsylvania

James P. Connolly
Regional Director
14 South Ascot Court
Newtown, PA 18940

Home: (215) 968-3976
Cell: (215) 290-7623
Fax: (215) 968-6592
Email: jimpcon@erols.com

John R. McGinley, Jr., Esq., Chairman
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Chairman McGinley,

My name is Jim Connolly and I am the state of Pennsylvania, Chapter Director for The National Alliance of Methadone Advocates (PA-NAMA). I am also a Regional Director for NAMA and those duties consist of the oversight and mentoring of existing NAMA Chapters in the state of PA and surrounding states.

The purpose of this letter is to respectfully request that the Independent Regulatory Review Commission disapprove Chapter 715 Standards for Narcotic Treatment Programs as submitted by the PA Department of Health.

PA-NAMA supports the need for new methadone treatment regulations here in the state of PA but we are against the acceptance of Chapter 715 as recently submitted. The regulations as submitted show no new benefits to any interested parties, especially the patients, for whom the regulations impact the most.

Two keys points of the regulations that I feel are unreasonable and in no way follow any "Best Practices" are the counseling requirements and takehome medication.
PA-NAMA recognizes the need for counseling for patients that need it. However, having a long term, stable patient be required to attend and PAY for counseling that is no longer needed is in appropriate and a waste of money.
Treatment, which includes counseling, needs to be individualized according to the needs and wants of each individual patient.

The next point of contention is takehome medication. Patients who are stable in their treatment and meet the criteria for takehome medications should be allowed more that just 6 takehome doses per week. The new Federal Regulations that have the oversight of the Center for Substance Abuse Treatment (CSAT) allows up to 30 takehome doses of

medication for those patients that meet the criteria. These extended takehomes policies have already been shown to be working well in other states.
There is no justifiable reason that patients enrolled in Narcotic Treatment Programs in the state of PA be denied having extended takehomes if the criteria is met.
With regards to the criteria, there is no reason to make it any stricter than what has already been established by CSAT.

CSAT, over the past 10 years, has developed "Best Practices" procedures for treatment of patients enrolled in Narcotic Treatment Programs. These procedures were developed using the best and most knowledgeable sources available. Experts in the field of addiction medicine and methadone treatment were used to develop these procedures.

PA-NAMA strongly urges the State of Pennsylvania to adopt these procedures, that are in the Federal Regulations and Guidelines (Part 42 Chapter 8), as written and make them the state of Pennsylvania's Narcotic Treatment Program Standards.

Thank you very much for your consideration in this matter.

Respectfully,

James P. Connolly

URGENT

To:	IRRC
Voice Number:	
Fax Number:	17177832664
Company:	
From:	Jim Connolly
Company:	
Fax Number:	2159686592
Voice Number:	215-968-3976
Date:	9/24/02
Number of Pages:	3
Subject:	Comment on PA Methadone Regs Chapter 715
Message:	

Original: 2134

COUNTY OF NORTHAMPTON

DEPARTMENT OF HUMAN SERVICES

MENTAL HEALTH/MENTAL RETARDATION/DRUG & ALCOHOL DIVISION

KATHLEEN M. KELLY
ADMINISTRATOR

September 24, 2002

Robert Nyce, Executive Director
IRRC
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce:

1) Dispensing nurse staffing - Section 715.7 (1) requires one full-time nurse for each 200 patients. Most states do not have any requirement and we believe that computer-controlled dosing equipment permits a nurse to dose up to 300 patients (especially considering that many have take-home medication and don't come every day).

2) Dosing time - Section 715.7 (b) requires the program to dose every patient within 15 minutes of arrival. We believe that most patients can be dosed in that time but groups of 12 or 15 patients often arrive at closing time and that standard cannot be met. No other state has a similar requirement. This should be eliminated.

3) Counselor/patient ratio - Section 715.8 requires the same 35:1 ratio as for drug-free programs even though in methadone treatment patients often stay for years on reduced counseling schedules. It is impossible to generate enough revenue from 35 such patients to pay expenses for a full-time counselor including benefits and overhead. The regulation should either have no ratio (as in most states), go by counselor contact hours, or be 50:1 which is the federal recommendation.

4) Psychotherapy services - Section 715.19 requires all patients in treatment 2 years or less to get at least 2.5 hours per month of counseling. While we believe many patients need that, especially for the first year, others do not. For example, many new patients are readmissions of people who have already had years of counseling and really just need to resume medication. There needs to be room for clinical judgement of the medical director in regard to psychotherapy services to avoid wasting scarce resources. The proposed standard is more extreme than any other major state.

☐ Governor Wolf Building
45 N. Second Street
Easton, PA 18042-3637
Phone: (610) 559-3260
FAX: (610) 559-3755

☒ Martin J. Bechtel Building
520 East Broad Street
Bethlehem, PA 18018-6395
Phone: (610) 974-7500 / 974-7555
FAX: (610) 974-7596

5) Prohibition of medication units - Section 715.25 prohibits its patients from getting dosed at a site near their home (i.e., a satellite location) while continuing to travel to the program's main location for counseling and other services. Most states permit medication units and patients can more easily obtain employment if they don't have to travel very long distances daily just for methadone medication. The regulation should permit satellite dosing within reasonable restrictions.

I realize that the use of Methadone is a controversial treatment modality. However, it does not make sense to me to recognize an accepted treatment, and then regulate it to the point that it becomes inaccessible.

I respectfully request that consideration be given to the changes offered to the IRRC by the Methadone Treatment Providers.

Sincerely,

Mary E. Carr

Mary E. Carr
County of Northampton
SCA Director

Cc: Glen Cooper
Neal Byrnes

Original: 2134
IRRC

From: Kristina DelPrincipe [kdelprincipe@tadiso.org]

Sent: Tuesday, September 24, 2002 8:12 AM

To: IRRC

Subject: Chapter 715 Methadone Regulations

IRRC:
We are writing to support the Pennsylvania Association Methadone Provider's (PAMP) recommendations relating to Chapter 715 Methadone Regulations. We believe that the Pennsylvania regulations should be more in line with other states' regulations and the federal regulations regarding Opioid Treatment Programs. We believe that the proposed regulations, as written, create obstacles to the provision of quality services to our clients. Please consider PAMP's recommendations for revising Chapter 715.
Kristina A. DelPrincipe, Chief Financial Officer
Tadiso, Inc.

Original; 2134

PROGRESSIVE MEDICAL SPECIALISTS, INC.

9/23/02

Robert Nyce, Executive Director
Independent Regulatory Review Commission
333 Market Street, 14 th Floor
Harrisburg, PA 17101
717-783-2664

Dear Mr. Nyce,

This is in regards to the upcoming review of Chapter 717 methadone regulations. I am the Director of two Pittsburgh facilities.

I am in support of some of the items sent to you from PAMP. The items I support described by Glenn Cooper in the letter he sent to you dated 9/19/02 include the Psychosocial staffing, Narcotic treatment physician, Patient capacity, Physician staffing and Patient Termination. The only item that I do not agree with is take home privileges. The other items my clinics are indifferent too.

Thank you for taking the time to review my opinion on the new regulations,

Annamarie Roberto
Project Director Progressive Medical Specialists, Inc.

2900 Smallman Street
Pittsburgh, PA 15201

Phone: 412-391-6384
Fax: 412-391-7882

2453 West Pike Road
Houston, Pa 15342

Phone: 724-873-5655
Fax: 724-873-5656

Re-disclosure Prohibited

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

Progressive Medical

2900 Smallman Street
Pittsburgh, PA 15201
Phone: 412-391-6384
Fax: 412-391-7882

OK per JMS 9/23/02 called

Fax Transmittal Form

To Independent Regulatory Review Commission from Annamarie Roberto

Name: Review Commission
Organization Name/Dept:
CC:
Phone number:
Fax number: 717-783-2664

PMS-Pittsburgh Location
Phone: 412-391-6384
Fax: 412-391-7882

☐ Urgent
☐ For Review
☐ Please Comment
☐ Please Reply

Date sent: 9/23/02
Time sent: 10:45 am
Number of pages including cover page: 2

Message:

Attn: Robert Nyce

Original: 2134

COUNTY OF NORTHAMPTON

DEPARTMENT OF HUMAN SERVICES

MENTAL HEALTH/MENTAL RETARDATION/DRUG & ALCOHOL DIVISION

KATHLEEN M. KELLY
ADMINISTRATOR

September 24, 2002

Robert Nyce, Executive Director
IRRC
333 Market Street, 14th Floor
Harrisburg, PA 17101

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Phone: (610) 974-7500 / 974-7555
FAX: (610) 974-7596

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I respectfully request that consideration be given to the changes offered to the IRRC by the Methadone Treatment Providers.

Sincerely,

Mary E. Carr

Mary E. Carr
County of Northampton
SCA Director

Cc: Glen Cooper
Neal Byrnes

COUNTY OF NORTHAMPTON

DEPARTMENT OF HUMAN SERVICES

MH/MR/D&A
KATHLEEN M. KELLY
ADMINISTRATOR

FACSIMILE

To: IRRC / Robert Nyce

From: Mary Carr

Fax: 717 783 2664

Number of pages (Including coversheet): 3

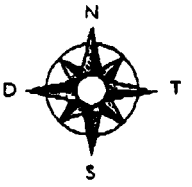
Comment:

"Corrected Copy"

MARTIN J. BECHTEL BUILDING
520 EAST BROAD STREET
BETHLEHEM, PA 18018
PHONE: 610-974-7555
FAX: 610-974-7596

Original: 2134

NEW DIRECTIONS
Treatment Services



September 23, 2002

Robert Nyce
IRRC, Executive Director
IRRC
333 Market St., 14th Floor
Harrisburg, PA 17101

Mr. Nyce,

I am writing to express my support for the changes recommended by the Pennsylvania Association of Methadone Providers to the proposed Chapter 715 methadone standards. There are several of the proposed changes that I believe merit particular attention.

Specifically:

Dispensing nurse staffing. Section 715.7 would require one full time dispensing nurse for every 200 patients. Most of the methadone providers have extensive experience with automated dispensing systems and know first hand that the 300:1 ratio espoused by PAMP is entirely realistic without compromising patient care in any way.

Counselor/patient ratio. The 35:1 counselor to patient ratio proposed in 715.8 might, on the surface, sound like a reasonable and well-intended guide to insure that methadone patients are served by counselors who not overburdened by excessive caseloads. In practice, however, there are many methadone patients who are long term stable individuals who meet existing and proposed standards with a monthly one hour group session. For such patients providing this level of service is both clinically appropriate and a judicious use of limited program resources. Bound by a 35:1 ratio that counts each patient the same regardless of whether he or she is getting four hours each month of individual counseling or one hour of group makes the flexible allocation counselor time impossible. For example, a counselor who conducts three monthly groups, each with ten different patients, under the proposed regulations, could only carry five additional patients, even though the groups would only require three hours a month of face-to-face time. Taking into account the long term nature of methadone treatment and the extensive use of group treatment a ratio of 50:1 is more than adequate to insure that methadone patients are provided ample counselor time and attention. An even more sensible approach, as proposed by PAMP, would be to base the ratio on actual face-to-face contact hours. While insuring that counseling staff have sufficient time to address the concerns of their patients, this would also allow the needed flexibility to allocate counselor's time where it will do the most good.

1810 Steelstone Rd., Suite 101
Allentown, PA 18109
(610) 264-5900 - phone
(610) 264-5907 - fax

20-22 N. 6th Ave.
Reading, PA 19611
(610) 478-0646 - phone
(610) 478-1671 - fax

Psychotherapy services. The requirement reflected in 715.19 for all patients to have 2.5 hours per month of counseling for the first two years of treatment is both unnecessary and counterproductive. As above, this requirement would appear to simply insure provision of adequate counseling services to patients. However, because it does not make a distinction between first time patients and those who may have been in methadone treatment on numerous prior occasions, providers are compelled to provide counseling services at what in many cases would be an inappropriate and wasteful level for up to 2 years to readmitted patients. The current proposal also does not take into acoount that some patients, even first time patients, achieve a sustainable abstinence from illicit drugs without an extended period of counseling. It would be more sensible and cost effective to apply this standard only to first time methadone patients, or to base any requirement for minimal counseling services on objective indicators of patient progress in treatment.

In reviewing the concerns described above I think it is important to note that in a practical sense the net aggregate effect of the department proposals is the mandatory waste of limited resources. This is simply not good policy considering that methadone is largely funded with public dollars. But my concern goes beyond that. We presently have over 100 heroin addicts waiting to get into treatment in our program in Allentown. Most of them are involved in daily criminal activity to support their untreated addiction. We are now admitting patients who contacted us in November of last year. The counselor and nurse ratios and the mandatory counseling minimums described above constitute the major obstacles to our admitting more people more quickly. Any measures taken to insure adequate staffing and service delivery levels must balance these concerns against the interests of those unable to access treatment because of what are clearly excessive safeguards.

Sincerely,

Neal Byrnes
Program Director

New Directions Treatment Services

Fax Transmission Cover Sheet

1810 Steelstone Road, Suite 101-102
Allentown, PA 18109
(610) 264-5900 - phone
(610) 264-8423 - fax

Number of pages including cover sheet: 3

Date: 9/23 *Time:* 3pm.

TO: *Name:* Robert Nyce

Organization: IRRC

Fax Number: 717-783-2664

FROM: *Name:* Neal Byrnes

Organization: New Directions Treatment Services

Comments: Please see attached comments regarding pending Chapter 715 methadone standards.

Thanks,
Neal Byrnes

clifax.frm

Proposed Regulations for Michaele Totino

8/13/2010 10:31:33 AM

IRRC No.	Reg No.	DEPARTMENT NAME REGULATION TITLE	Publication Date	Close of Public Comment	Issues List Due	Report to TL	Report Mailed	Comments Due	Commis	Analyst	Support
2854	14-519	**Department of Public Welfare** Child Care Facilities	06/26/10	07/26/10	08/10/10	08/15/10	08/18/10	08/25/10	SBL	FEW MAT	WBG
2857	7-459	**Environmental Quality Board** Oil and Gas Wells	07/10/10	08/09/10	08/24/10	08/29/10	09/01/10	09/08/10	SBL	FEW MAT	WBG
2861	53-9	**Joint Committee on Documents** Preliminary Provisions; Definitions	08/07/10	09/07/10	09/22/10	09/27/10	09/30/10	10/07/10	SDF	FEW MAT	WBG

Original: 2134

Pennsylvania Association of Methadone Providers

September 23, 2002

James Smith
IRRC
333 Market Street
Harrisburg, PA 17101

Dear Mr. Smith,

Accompanying is the information which you requested. These are all outpatient providers except for Kirkbride which is an inpatient provider. I feel absolutely confident the vast majority support PAMP's position on the regulations based on recent meetings and conference calls with members. I know that there are also nonmembers (such as ATS) which agree with us. None the less, it is possible that one or more members have stated support for the department's position. The department has put pressure, especially on providers like Alliance who are awaiting departmental approvals on projects/census increases, to support Chapter 715.

I've also enclosed an article exemplifying the problem of lack of access. This was published recently after two people from Wilkes-Barre on our waiting list died of overdoses.

If you need anything else please let me know.

Sincerely,

Glen J. Cooper
President

1810 Steelstone Road
Allentown, PA 18109
E-mail: pamp@ptd.net
610-264-5900
Fax: 610-264-8423

PAMP Membership 2002

Achievement through Counseling & Treatment (ACT I)	Philadelphia, PA
Achievement through Counseling & Treatment (ACT II)	Philadelphia, PA
Addiction Medicine & Health Advocates, Inc.	Philadelphia, PA
Aldie Foundation	Doylestown, PA
Alliance Medical Services	Pittsburgh, PA
Crozer-Chester Medical Center Methadone Program	Chester, PA
Drug Abuse Rehabilitation Program (DARP) - The Consortium	Philadelphia, PA
Discovery House	Pittsburgh, PA
Discovery House	Harrisburg, PA
Discovery House	Hermitage, PA
Discovery House	Cranberry Township, PA
Discovery House	Hatboro, PA
Family Center Program of Thomas Jefferson University	Philadelphia, PA
Goldman Clinic North Philadelphia Health Systems	Philadelphia, PA
JFK Substance Abuse Treatment Program	Philadelphia, PA
Kirkbride	Philadelphia, PA
New Directions Treatments Services	Allentown, PA
New Directions Treatment Services	Reading, PA
Progressive Medical Specialists, Inc.	Pittsburgh, PA
Progressive Medical Specialists, Inc.	Houston, PA
TADISO, Inc.	Pittsburgh, PA
Narcotic Addiction Rehabiliation Program of Thomas Jefferson University	Philadelphia, PA

From Wilkes-Barre area's "Times Leader" newspaper

A fight to improve their lives

"To die while waiting in line for treatment is an obscene thing that should not happen in a civilized society."

Glen Cooper
New Directions clinic director

By TERRIE MORGAN-BESECKER
tmorgan@leader.net

He awakes each day at 7 a.m. and faces the same choice: 80 miles or a hypodermic needle.

His name is Dominick. He's a recovering heroin addict.

The needle, he knows, once put him in jail for two years. He knows it hurt his family. He knows it destroyed part of his heart, and nearly killed him with overdoses twice.

And he knows he'd probably shoot up again — if not for that 80-mile drive to the clinic in New Jersey.

That's where he obtains methadone. It's a drug he and his 24-year-old girlfriend, Kara, also a recovering addict, said blocks their cravings.

But each day is a struggle, the Wilkes-Barre-area couple said, as they fight their addictions and the obstacles they face in obtaining help.

Despite nearly four years of planning, Luzerne County does not have a methadone clinic, forcing dozens of local addicts to travel to surrounding areas for treatment.

At least 25 Luzerne County residents remain on a 120-person waiting list at the primary methadone provider for this area, the New Directions clinic in Allentown, said the center's director, Glen Cooper.

In the meantime, drug addicts continue to die at an alarming rate in the county. The number of suspected or confirmed drug deaths since January

See FIGHT, Page 4A

FAX TRANSMISSION

PENNSYLVANIA ASSOCIATION OF METHADONE PROVIDERS
c/o New Directions Treatment Services
1810 Steelstone Road
Allentown, PA 18109
610-264-5900
Fax: 610-264-8423

To:	James Smith IRRC	**Date:**	September 23, 2002
Fax #:	717-783-2664	**Pages:**	4, (including cover sheet)
From:	Glen J. Cooper President		

Original? 2134

New Directions Treatment Services
20-22 North Sixth Avenue
West Reading, PA 19611
(610) 478-0646 - phone
(610) 478-1671 - fax

Number of pages including cover sheet: 3

Date: 9-23-02 **Time:** 4:30 pm

TO: ***Name:*** Robert Nyce.
Organization: IRRC
Number: 717-783-2664

FROM: ***Name:*** Mairéad Desmond

COMMENTS: Please give this to Mr. Nyce before 10 am 9/24/02

NEW DIRECTIONS
Treatment Services

Original: 2134

23rd September, 2002,

Robert Nyce, Executive Director,
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce,

These comments are in response to the proposed, final form Chapter 715 methadone regulations that are before IRRC.

In addition to my comments on the specific issues addressed below, I have two other concerns related to this process.

- The proposed regulations were not posted on the Web. What provisions were made to make them accessible to consumers and what efforts were made to educate consumers about the proposed changes and the process involved?
- When I contacted the DOH Drug and Alcohol Licensing Division on 9/20/02 to inquire about the web location of the proposed regulations, Ms.Carol Bashore said that the comment period was over although comments will be accepted until 10:00 a.m. on 9/24/02. I am concerned that consumers may have missed an opportunity to comment if provided with the same information.

As program Director of a clinic in a location described by many in the community as being "in the middle of a heroin epidemic", I believe many of the proposed regulations to be burdensome, expensive to implement and not in keeping with the recent Federal revisions of methadone regulations. Therefore I request that the Commission disapprove the following sections of the proposal:

Dispensing nurse staffing-Section 715.7(a) requires one full-time nurse for each 200 patients. Most states do not have any requirement and I believe that computer-controlled dosing equipment permits a nurse to dose up to 300 patients (especially considering that many have take-home medication and don't come every day).

Dosing time-Section 715.7(b) requires the program to dose every patient within 15 minutes of arrival. Most of our patients are dosed within that timeframe but groups of 12 or 15 patients often arrive at closing time and this standard cannot always be met. No other state has a similar requirement. This should be eliminated.

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Counselor/patient ratio-Section 715.8 requires the same 35:1 ratio as for all other Outpatient Chemical Dependency Treatment programs. Methadone treatment programs target long-term drug abusers and therefore retain patients for longer periods than other treatment modalities. As patients progress, their counseling is reduced. It is impossible to generate enough revenue from 35 long-term patients to pay expenses for a full-time counselor including benefits and overhead. Counselor caseload should be based on the individualized treatment needs of each patient. The Federal recommendation is 50:1.

Psychotherapy services-Section 715.19 requires all patients in treatment 2 years or less to get at least 2.5 hours per month of counseling. Prescribing counseling contacts is not in keeping with individualized treatment. A client's progress in treatment and current needs are better indicators of the level of services necessary and therefore should be based on the clinical judgement of the professional staff

Prohibition of medication units-Section 715.25 prohibits patients from receiving medication at a site near their home (i.e. a satellite location) while continuing to travel to the program's main location for counseling and other services. Most states permit medication units. Pennsylvania is primarily a rural state, and many of our patients must travel long distances (daily in the early phases of treatment) for medication. This makes maintaining employment and meeting family and other obligations difficult and inhibits the clients' return to normal functioning.

715.6 Physician Staffing
The proposed 10:1 ratio is excessive and unnecessary as evidenced by requirements in other states. To argue that free-standing methadone clinics should also be primary care providers and become involved in the specialized medical interventions that are required for the treatment of HIV/AIDS and Hepatitis C is unreasonable. Through the use of appropriate referral and consultation our patients can access physical health care through contracted physical health care providers. Our contracts with Health Choices HMOs are for behavioral health services, physical health services would not be reimbursed.

715.16 Take Home Privileges
The proposed schedule is not in keeping with Federal recommendations. Within Federal guidelines, the licensed physician who is prescribing the medication should make medication decisions.

Thank you for the opportunity to comment on these proposed regulations.

Sincerely,

Mairead Desmond
Program Director, NDTS West Reading.

Original: 2134

METHADONE AWARENESS

PATIENT ADVOCACY NEWSLETTER & ORGANIZATION

33 s. Glenwood Avenue

Aldan, PA 19018

METHADONE AWARENESS IS MADE POSSIBLE BY YOUR SUBSCRIPTIONS AND INDIVIDUAL DONATIONS.

M.A. is the official East Coast newsletter of NAMA - the *National Alliance of Methadone Advocates*, and is distributed nationally with a circulation of 10,000 readers worldwide.

Attention:
Mr. Robert Nyce
Executive Director—Independent Regulatory Review Committee
333 Market Street
14th Floor
Harrisburg, PA 17101

Monday, September 23, 2002

Dear Mr. Nyce,

I am writing to you in reference to the packet of information I received regarding the changes to the proposed regulations for the standards for approval of narcotic treatment programs. I am hoping that this letter will make its way to you in time for the hearing on Thursday.

As Editor and Publisher of Methadone Awareness I would like to go on record as stating that myself, and the patients I represent, are not happy with the proposed changes.

I feel there was not enough input from methadone maintenance consumers—ie: the patients. Nor are the proposed changes to the regulations in any way patient friendly. The take-home policies, in particular, are way out of line with the federal regulations and standards, and need to be seriously revised.

Please feel free to contact me if necessary.

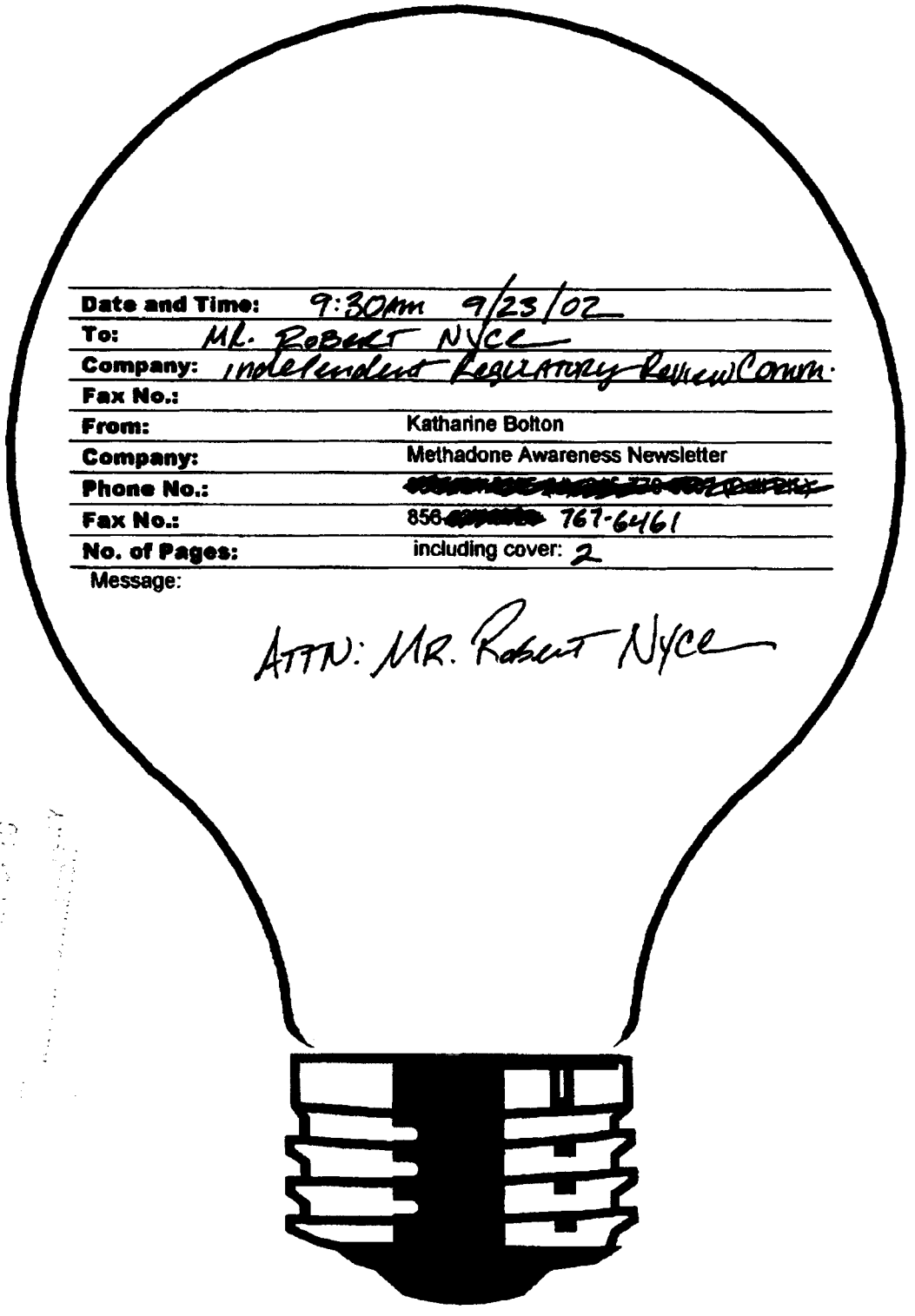
Sincerely,
Katharine Bolton
Cell Ph– 609-647-7073

Fax: 856-767-6461 E-mail: KB4MA@AOL.COM

Date and Time:	9:30am 9/23/02
To:	Mr. Robert Nyce
Company:	Independent Regulatory Review Comm.
Fax No.:	
From:	Katharine Bolton
Company:	Methadone Awareness Newsletter
Phone No.:	[redacted]
Fax No.:	856-[redacted] 767-6461
No. of Pages:	including cover: 2

Message:

ATTN: MR. Robert Nyce



GREAT IDEA!

Thomas Jefferson University | Jefferson Medical College

Department of Pediatrics
Maternal Addiction Treatment
Education & Research

1201 Chestnut Street
9th Floor
Philadelphia, PA 19107
215-955-1951
Fax: 215-568-6414

September 23, 2002

Original: 213

Robert Nyce
Executive Director
Independent Regulatory Review Commission
333 Market St, 14th Fl
Harrisburg, PA 17101

Dear Commissioners and Staff:

Enclosed are comments to the proposed Final Rule, Chapters 701 and 715. Although I fully appreciate that the proposed regulations are the result of considerable time and deliberation, it is of concern that they do not reflect the 1995 recommendations of the Institute of Medicine pertaining to the regulation of methadone treatment nor are they consistent with the Drug Addiction Treatment Act of 2000 and the Code of Federal Regulations 42 Part 8 published in January 2001.

Specifically:

- 715.1 General provisions (a)

  This provision is in direct conflict with the Drug Addiction Treatment Act of 2000 which allows qualified office based physicians to dispense specially approved schedule III, IV and V narcotic medications for the treatment of narcotic addiction.

- 715.4 Denial, revocation or suspension of approval

  This section only addresses the right of the department to deny, revoke or suspend approval. No provision is included for an appeal process. The right of appeal should be fundamental to the process. Not only does 42CFR Part 8 recognize the need for appeal procedures, providers are required to include an appeal process for patients in their Policy and Procedure manual.

- 715.12 Informed consent (5)

  This statement should read "that methadone is transmitted to the unborn child and *may* cause physical dependence." Numerous research studies have found that not all infants exposed to methadone in utero exhibit withdrawal.

- 715.14 Urine testing

  This section should not be specific to urine, as there are new technologies emerging using other fluids that may be as sensitive and specific as urine tests.

- 7715.16 Take-home privileges

This regulation is of special concern as it is significantly more restrictive than the federal regulation. There is often a case to be made that a more rigorous regulation provides for a better standard of care. However, in this case, the opposite is true and there is the potential for harm. The Federal regulation allows for 30-day take homes after 2 years in treatment whereas this regulation would only allow a 6-day take home after 3 years in treatment. Such a limited take home privilege does not reflect an understanding of successful methadone maintenance treatment and the ability of some patients to be in recovery while still requiring medication. This regulation is punitive to a patient who has maintained a successful recovery and may well be a disincentive for patients to remain in medication assisted treatment, thus leading to a high probability of relapse.

- 715.19 Psychotherapy services

  While it is recognized that the intent of this regulation is to insure that services are provided, the result of specifying the number of hours required per month per years in treatment is to take treatment out of the purview of the clinician. The length of time in treatment is not the issue but rather how the patient responds to the therapeutic process. While some patients will require more intensive psychotherapy than required, others may be very successful in treatment and require less. To regulate how much psychotherapy a patient must receive after 2,3 and 4 years of treatment is not supported by 42 CFR Part 8, or by the American Association for the Treatment of Opioid Dependence.

- 715.25 Prohibition of medication units

  This prohibition is extremely restrictive given the limited availability of medication-assisted treatment in areas other than the western and southeastern sections of the Commonwealth. It is unclear why this regulation is proposed since medication units are part of treatment programs and it may limit and/or impede access to treatment for a significant number of persons.

I respectfully request that the proposed regulations be changed to address these concerns.

Sincerely,

Karol Kaltenbach, PhD
Clinical Associate Professor of Pediatrics,
Psychiatry and Human Behavior
Director, Maternal Addiction Treatment Education and Research

Embargoed

Original: 2134

September 23, 2002

John R. McGinley, Jr. Esq., Chairman
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Chairman McGinley,

The purpose of this letter is to request on behalf of Aldie Counseling Center that the Independent Regulatory Review Commission disapprove Chapter 715 Standards for Narcotic Treatment Program as submitted by the Department of Health.

It is important to note that Aldie Counseling Center supports the need for new methadone regulations; however, we oppose the adoption of Chapter 715 as recently published. We believe the regulations, as submitted, are unreasonable, costly to the Commonwealth and are not in the best interest of public health, safety, and welfare of Pennsylvania citizens.

Since 1998, I have directed two methadone maintenance programs and am quite familiar with the complexities of providing this treatment modality. The value of methadone maintenance as a treatment modality is well documented in the literature and the need for expansion of methadone services in Pennsylvania is clear. The increasing number of opiate dependent individuals seeking treatment demands an expansion of methadone services a critical review of the way in which these services are provided, as well.

The following three areas in the Chapter 715 submission are cumbersome and present significant hardship for programs attempting to offer methadone services:

715.8 Psychosocial Staffing

The counselor to patient ratio of 35:1 is inappropriate for Methadone Programs. This regulation forces methadone programs to operate on the same general principles as traditional outpatient clinics. Methadone programs are very different from traditional outpatient clinics—patients tend to stay in treatment for long periods of time and, once stable, do not require high levels of counseling services. We support the recommendation a counselor to patient ratio of 50:1 which is more appropriate to the treatment modality.

715.19 Psychotherapy services

The same level of counseling (number of hours) is required whether a patient is newly in treatment and not yet stable or has been in treatment for 2 years and is stable (employed, illicit drug-free, and completed 2 years of weekly individual and group counseling). This is a waste of the limited resources available for the treatment of opiate-dependent individuals. The proposed regulations do not apply to the methadone maintenance treatment modality.

715.7 Dispensing or administering staffing

There is no rationale (data) for the one full-time dispensing staff for 200 patients. Neither acceditation standards nor most other states specify this ratio. This ratio is arbitrary—the Department has failed to provide any data to support how the ratio was developed nor whether the ratio is reasonable or appropriate in any way to protect public health, safety and welfare. The 15-minute time period dosing is also arbitrary and does not reflect input from methadone treatment providers.

The above areas in the Chapter 715 submission are especially problematic. With consistently diminishing resources, an increasing patient population and changes within the patient population, Chapter 715 places undue restrictions on treatment providers. Methadone treatment providers must be given a voice in regulations that directly affect their daily work with patients. The IRRC should disapprove the regulations as submitted and the Department of Health should be asked to revise the items listed above after taking into account the concerns of those most knowledgeable in the field.

Sincerely,

Evelyn Estacio, L.S.W., M.B.A.
Supervisor, Drug and Alcohol Treatment
Bucks County Department of Corrections

Orignal: 2134

September 23, 2002

John R. McGinley, Jr., Esq., Chairman
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, Pennsylvania 17101

Dear Chairman McGinley:

The purpose of this letter is to request on behalf of Aldie Foundation, Inc., that the Independent Regulatory Review Commission disapprove Chapter 715 Standards for Narcotic Treatment Program as submitted by the Department of Health.

Aldie Foundation has provided family counseling services for 25 years to persons struggling with chemical dependence, and has provided methadone treatment for the last five years.

It is important to note that Aldie supports the need for new methadone regulations; however, we oppose the adoption of Chapter 715 as recently proposed. We believe that the regulations as submitted are unreasonable, costly to the Commonwealth, and are not in the best interest of public health, safety, and welfare of Pennsylvania citizens. . In particular, the areas of most concern are:

- The psychosocial staffing ratio – Since patients in methadone programs tend to require long-term treatment and reduced counseling schedules over time, mandating artificial staff-to-patient ratios is inappropriate.
- Requirements for minimum psychotherapy services have the same basic problem. They are arbitrary and do not take into consideration the needs of the patient. These clinical decisions need to be driven by medical necessity, not by arbitrary regulation.
- Regulation against the establishment of medications units unnecessarily reduces accessibility of methadone services to patients, especially those in rural areas. Such regulations may also be contrary to pharmacist practice rights and may invite litigation.
- The language specifying one FTE dispensing nurse per 200 patients is overly restrictive, and the language specifying 15-minute time limitations is absurd, arbitrary, and has no relation to the reality of patient/physician care or the idiosyncrasies of a patient's needs. Evaluation of appropriate dose, program compliance, and patient progress, often needs to occur prior to medication dispensing in order to assure responsible medical practices.

We urge that you reject the Chapter 715 standards as submitted.

Sincerely,

Michael M. Ratajczak
Executive Director

jm

IRRC Original: 2134

From: Aldie Foundation [aldie@erols.com]

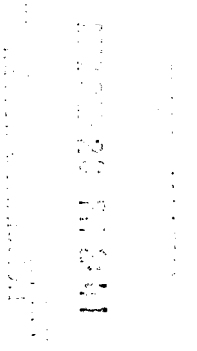
Sent: Monday, September 23, 2002 2:23 PM

To: IRRC

Subject: Methadone Regulations

Dear Mr. McGinley,
Please see attached document re: Methadone 715 regs. Fax copy also being sent. Do you need original hard copy as well? Thank you for your attention to this matter.
Michael Ratajczak
Executive Director,

Aldie Foundation, Inc.
228 N. Main St.
Doylestown, PA 18901
215-345-8530 Ext. 110



September 23, 2002

John R. McGinley, Jr., Esq., Chairman
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, Pennsylvania 17101

Dear Chairman McGinley:

The purpose of this letter is to request on behalf of Aldie Foundation, Inc., that the Independent Regulatory Review Commission disapprove Chapter 715 Standards for Narcotic Treatment Program as submitted by the Department of Health.

It is important to note that Aldie supports the need for new methadone regulations; however, we oppose the adoption of Chapter 715 as recently published. We believe that the regulations as submitted are unreasonable, costly to the Commonwealth, and are not in the best interest of public health, safety, and welfare of Pennsylvania citizens.

Aldie Foundation has provided family counseling services for 25 years to persons struggling with chemical dependence, and has provided methadone treatment for the last five years.

We support the need for new methadone regulations, but strongly recommend disapproval of the regulations as currently proposed. The regulations as submitted do not represent the needs of patients or providers, do not represent Federal initiatives currently being undertaken, and contradict best practices as suggested by experts in the field. In particular, the areas of most concern are:

- The psychosocial staffing ratio – Since patients in methadone programs tend to require long-term treatment and reduced counseling schedules over time, mandating artificial staff-to-patient ratios is inappropriate. The language specifying one FTE per 200 patients is overly restrictive, and the language specifying 15-minute time limitations is absurd, arbitrary, and has no relation to the reality of patient/physician care or the idiosyncrasies of a patient's needs. Evaluation of appropriate dose, program compliance, and patient progress, often needs to occur prior to medication dispensing in order to assure responsible medical practices.

- Requirements for minimum psychotherapy services have the same basic problem. They are arbitrary and do not take into consideration the needs of the patient. These clinical decisions need to be driven by medical necessity, not by arbitrary regulation.

- Regulation against the establishment of medications units unnecessarily reduces accessibility of methadone services to patients, especially those in rural areas. Such regulations may also be contrary to pharmacist practice rights and may invite litigation.

We urge that you reconsider Chapter 715 standards and make appropriate revisions.

Sincerely,

Michael M. Ratajczak
Executive Director

Embargoed

PARKSIDE RECOVERY

Saving Lives "One Day At A Time"

5000 PARKSIDE AVENUE
PHILADELPHIA, PA 19131
PHONE 215-879-6116 FAX 215-879-0196

September 20, 2002

Robert Nyce, Executive Director
I.R.R.C.
14th Floor, 333 Market Street
Harrisburg, PA 17101

RE: Methadone Regulations

Dear Mr. Nyce,

This letter is written in support of the updated Methadone regulations. The current regulations are hopelessly outdated and are in many ways negative to the field. The new regulations are a good first step in bringing the Commonwealth into the forefront of reasonable and appropriate pharmacotherapy regulations. Parkside Recovery is a large not for profit Methadone provider in Philadelphia. The program currently provides treatment support to approximately 600 people per day. Parkside Recovery views itself as primarily a counseling program with medical and pharmacotherapy being considered as secondary services. In this regard, the new regulations do not, for the most part, appear problematic for the program's operations. Our concerns and issues about the new regulations are as follows:

- **Federal Mandate for Accreditation**-Any and all new regulations should support and be consistent with the Opiate Treatment Program Guidelines and Accreditation Standards. We believe that the concepts of the new regulations are consistent in philosophy; however, we hope the Department's focus will be more outcome focused.

- **Termination of Non-Payment**-We fully support the new regulations position on non-payment. We do not believe that non-payment should be a sole determinate for administrative termination.

- **Nursing Ratio**-We support the ratio change and agree, especially with the dispensing technology utilized by Parkside, that 200:1 or higher is appropriate.

- **Counselor Ratio**-The recovery treatment model utilized by Parkside requires reduced counselor to client ratios so the 35:1 is not problematic. We do urge the Department calculate the counselor capacity as an aggregate rather than by individual staff person.

- **Physician Ratio**-We support the physician ratio. Again the Recovery model calls for heavy physician involvement in the treatment process and we utilize a ratio less than 10 clients to 1 physician hour.

- **Fifteen Minute Dispensing Visit**-We agree that this is an appropriate goal for all providers but cannot support this part of the regulations. The Parkside model operates under a 'Safe Haven' concept so we disallow all weapons in the facility. To insure this policy is followed we actually utilize a metal detector. The usage of a metal detector slows the dispensing process so we can never achieve an absolute 15-minute visit.

We are pleased that new regulations have been developed and believe that the new regulations are much improved over the existing rules. We further believe that the new regulations have many improvements and are more in line with current Best Practices among Opiate Treatment Programs. We are concerned over the dispensing requirement and some duplication apparent with the Accreditation standards but otherwise support the new regulations.

Sincerely,

John T. Carroll
Vice President of Addictive Diseases

PHONE 856-757-9190 FAX 856-338-1892 WEB: www.nhsonline.org

FACSIMILE TRANSMITTAL SHEET

TO: ROBERT NYLE	FROM: JOHN S. CARROLL
COMPANY: IRRC	DATE: 9/24/02
FAX NUMBER: 717-783-2664	TOTAL NO. OF PAGES INCLUDING COVER: 3
PHONE NUMBER:	SENDER'S REFERENCE NUMBER:
RE:	YOUR REFERENCE NUMBER:

☒ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

413 BROADWAY, CAMDEN, NJ 08103
PHONE: 856.757.9190
FAX: 856.338.1892

IRRC

From: Smith, James M.
Sent: Friday, September 20, 2002 12:43 PM
To: IRRC
Cc: Sandusky, Richard M.; Markham, Christopher L.
Subject: FW:

Original: 2134

IIRC.doc

Comment on #2134

-----Original Message-----
From: JKegley@aol.com [mailto:JKegley@aol.com]
Sent: Friday, September 20, 2002 12:08 PM
To: Smith, James M.
Subject: Re:

Jim, my comment letter is attached. I hope it is in time for consideration.

Jeff Kegley

September 20, 2002 Original: 2134

Chairman John R. McGinley, Jr.
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Chairman;

I am submitting formal comment regarding regulations proposed by the Department of Health, Standards for Approval of Narcotic Treatment Programs (IRRC Number 2134) representing Advanced Treatment Systems, Inc., Coatesville, PA. ATS has been a licensed narcotics treatment program since May 1998.

By way of introduction, I am a Pennsylvania Licensed Social Worker, have been in the addictions treatment field since 1969, and currently serve as an Opioid Treatment Program surveyor for CARF, one of the federally approved accrediting bodies for such programs across the country.

The Department's proposed regulation has developed at a pace behind national progress in the field. We believe the Department should review these developments and update proposed regulations.

These changes in the field of narcotics addiction treatment are due to both increases in *science* and in *demand* for services directly related to greater numbers of opioid addicted individuals across the country, including Pennsylvania. The greatest change in the field relates to how the Federal Government regulates such programs. Formerly supervised by the Food and Drug Administration, such programs are now under supervision of SAMHSA's Center for Substance Abuse Treatment (CSAT), Office of Pharmacologic Therapies.

After lengthy review of the old regulations and rules for federal oversight, CSAT determined that methadone treatment facilities should begin to be considered as part of mainstream healthcare. To this end, CSAT implemented rules requiring independent accreditation (JCAHO, CARF, etc.) for all such providers across the country. They simultaneously developed treatment standards in accordance with *best practice guidelines*. While we support the Department's efforts to update these regulations, our hope to see more of these guidelines reflected in the final product.

The following comments reference specific proposed regulations:

701.1 Definitions; Narcotic treatment physician.

This level of training requirements is excessive and will serve to discourage physicians from working in clinics. Note that Buprenorphine rules require only 8 hours of training before being approved to treat heroin addicts in a primary care practice.

715.5 Patient Capacity

Most states do not regulate patient census; the Department's current regulation of census results in waiting lists at most clinics. The Department should either develop standards permitting interim maintenance or develop strategies to assure the elimination of waiting lists due imposed limits on capacity.

715.6 Physician staffing

Physicians, Nurse Practitioners and Physician's Assistants are already regulated by the Department of State. It is unnecessary for the Department of Health to impose additional rules for the treatment of opioid addiction. By doing so, the field of narcotics addiction treatment is further stigmatized among such licensed practitioners.

715.7 Dispensing or administering staffing

Increasing nursing FTE's does nothing to improve quality or efficiency of operations in a clinic. However, the number of dispensing stations does both. This regulation will allow providers with only one dispensing station to continue experiencing long waiting lines while having more nursing FTE's than available nursing duties.

715.8 Psychosocial Staffing

The Department is correct in its desire to assure psychosocial services to patients. However, this standard is excessive. This proposed standard fails to take into consideration the longevity of patients in treatment. Currently, patients who have completed their psychosocial treatment are thought to have the same therapy needs as a newly admitted patient. In reality, such patients continue participation in the clinic only because the clinic is the only place they can receive their medication. Adhering to a ratio of 1 to 35 destroys productivity standards for counselors, is wasteful of limited resources, and forces patients without the need for counseling to endure sessions they consider ridiculous.

715.16 Take Home privileges

It is clear that the stigma associated with heroin addiction influenced development of this regulation. There is no evidence that such patients divert medication to the illicit market. Patients with long-term demonstrated success in treatment should be permitted "take home" medication according to the schedule proposed by CSAT. This regulation in particular will result in patients crossing state lines to obtain take home privileges.

For those patients who have proved that "treatment works" and have "recovered" from the addicted lifestyle they had at the time of admission, the clinic environment itself is the most deviant they visit. A comparable example would be for recovering alcoholics being required to visit a Detox center daily.

715.21 Patient Termination

Healthcare providers should not be prohibited from discharging persons who no longer pay for their services.

In summary, we are requesting that final approval of this proposed regulation be delayed and that Department seek input from a "blue ribbon panel" of current providers, CSAT officials, and national experts to reframe designated standards. We are aware that IIRC procedures allow a 45-day period to accomplish this.

I expect to attend the hearing on September 26, 2002.

Sincerely,

Jeffrey J. Kegley
Executive Vice President

Embargoed

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Original: 2134

September 20, 2002

John R. McGinley, Jr., Esq., Chairman
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Chairman McGinley:

The purpose of this letter is to strongly recommend that the Independent Regulatory Review Commission disapprove *Chapter 715 Standards for Narcotic Treatment Programs*, as prepared and submitted by the Pennsylvania Department of Health.

The Bucks County Drug & Alcohol Commission, Inc. (BCDAC, Inc.) serves as the Single County Authority responsible for facilitating the provision of a comprehensive and balanced system of quality substance abuse prevention, intervention and treatment services for county residents. BCDAC, Inc. seeks to eliminate addiction, alleviate its effects and ultimately eliminate the abuse and misuse of alcohol, tobacco and other drugs in the county.

It is important to note that, while BCDAC, Inc. supports the need for revised methadone regulations to match the changes in federal regulations, we oppose the adoption of Chapter 715 as recently released on the basis that it is too restrictive. We in Bucks County have the unfortunate distinction of representing a region that is number one, nationally, in hospital emergency room visits due to opiate use. This region also has a high mortality rate related to narcotic abuse. Additionally, we have a great and growing gap of narcotic dependent individuals who cannot access treatment due to inadequate funding and inadequate treatment options. The problem of narcotic dependency is epidemic, as you no doubt know. Our efforts to educate our community at large, including consumers, providers and even state licensing bodies are numerous, but we need supportive laws and regulations to ensure that quality, cost effective and science based treatment options are available. Pharmacotherapy (including methadone) is an evidenced based treatment approach that we desperately need to expand in our region.

Most recently, our agency received a federal technical assistance grant from the Center for Substance Abuse Treatment, an arm of the Substance Abuse and Mental Health Services Agency (SAMHSA). We provided an intensive two-day conference entitled *Pharmacotherapy and Narcotic Dependency: Best and Promising Practices*, held September 9 and 10, 2002, in Langhorne, Bucks County. Nationally recognized experts in the field of narcotic dependency and pharmacotherapy, as well as consumer advocates, provided much-needed education regarding the best and promising practices. We will be continuing this technical assistance effort as we support programs to expand and provide more options for clients and families desperate for appropriate and effective treatment options. With all that science has to offer in our field and as acknowledged by the change at regulations at the federal level, we are deeply concerned that our own state Department of Health is proposing regulations that fly in the face of best practice standards and are not sensitive to the individual needs of clients.

We respectfully request that the proposed regulations be disapproved and revised by the Department of Health. The following is a listing of the some of the areas that we feel need to be re-written:

1. 715.8 Psychosocial Staffing

We feel that the proposed ratio of 35:1 is unreasonable for methadone programs. Although we do not believe that it is necessary to set a ratio and many states do not. A 50:1 would be more reasonable, if we must go with one. A larger ratio has been recognized as a best practice standard because all programs have a balance of individuals who need intensive treatment focus, as well as clients with many months and years of sobriety who no longer need intensive treatment but are self-sufficient, tax paying and law abiding community members. The PA Department of health's proposed regulation is unnecessarily restrictive and a cost driver for our treatment system.

2. 715.19 Psychotherapy Services

Pharmacotherapy is a highly individualized treatment regiment. Clients, who have demonstrated their sobriety through life changes, and a variety of other commitments, should not be held to the same standard as a client just entering this treatment regimen. They need fewer treatment episodes on average and certainly do not need the level as proposed in these regulations. The federal government has acknowledged this in their regulations, as do pharmacotherapy best practice standards. One way to approach this would be to exclude individuals with an agreed upon level of seniority in the program from this ratio requirement.

On another level, nowhere else in laws or regulations is there a requirement that a client receive a certain level or amount of treatment, whether they need it or not. Best practice standards indicate that the qualified professionals who are working with clients should individualize treatment to patient need. Sometimes this means placing the client in a higher level of care, including residential, partial hospitalization and intensive outpatient services. On the back end, however, most clients need very little formal therapy after they have been maintained on medication for a number of months. Certainly this would also be true for clients on medication for two or three years and more.

As a payer for services, we are also seriously concerned as to the financial impact of this therapeutic requirement. We are unable now to pay for all of the services provided within treatment programs for clients eligible for Medicaid funding or for other state and federal public dollars. Thus clients would most likely end up paying for a service that is not only unnecessary, but also intrusive and counter to our goal of self-sufficiency within the community. Does it make practical or clinical sense to require the same level of therapy for a new client as for someone who has been in the program for two years? We think not.

3. ***715.25 Prohibition of Medication Units***

Medication units are essential to pharmacotherapy treatment. The federal definition of this level of care states that the medication units are part of a comprehensive narcotic treatment program. Thus any medication unit operating within this definition and federal regulation would be part of a larger agency that would provide a full range of clinical services at its main site. With few pharmacotherapy clinics available to those who need them now, medication units operating within the new federal guidelines presents a very important option to us. One such unit is now being proposed in Lancaster and we are hoping to start one in our county later this year.

Clients in methadone treatment usually have to pick up their medication six days of the Week. Even in a suburban area such as ours, this can mean a 45-minute drive to a clinic, before driving on to work. This is day in and day out, 52 weeks a year. We know that requiring them to come back additional times for therapy and other support services is extremely difficult, particularly if the client does not have private transportation. One sensible option is to allow clients to pick up their medication at a local pharmacy or other appropriately licensed entity as defined under the federal regulations as a medication unit. Then they would only need to come to the clinic for their therapy.

We should note that transportation costs are a major cost driver for public funded treatment. We are already now paying tens of thousands of dollars to transport clients on a daily basis to and from a centrally located methadone clinic due to lack of adequate public transportation. Transportation is a real barrier to treatment for many folks here and I imagine that it is much more so in rural parts of this state.

We strongly object to the Pa Department of Health's current effort to prohibit our local and best practice efforts to expand availability of an important treatment alternative and to make treatment more accessible to clients.

4. ***715.7 Dispensing or Administering Staffing***

The proposed 200 patient limit is unreasonable. We have not located any research-based evidence, which stipulates that any limit must be imposed, nor do the federal regulations acknowledge this need. In addition, we disagree with the proposed 15-minute time period for dosing.

Last, but certainly not least, we feel it is imperative that the field be involved throughout the process of development and adoption of new regulations. We do not feel that consumers have sufficiently and in good faith been involved in the consideration of these proposed regulations. Nor do we feel that the thoughts and concerns of those professionally involved in the treatment of clients with a narcotic dependency have been carefully considered.

We deeply respect your Independent Regulatory Review Commission's task of addressing narcotic treatment. We ask that you carefully consider our remarks and those of other advocacy organizations. The proposed regulations are not in the best interest of our clients, nor do they match the intention of our lead agencies responsible for financing of treatment for narcotic dependency.

I am sending via a separate mailing a packet of information from our recent conference for your review. I am available to further illustrate our concerns with the Pennsylvania Department of Health's proposed regulations, and appreciate, in advance, your consideration of the concerns we raise on behalf of the consumers of Bucks County.

Sincerely,

Margaret E. Hanna
Executive Director

Enclosure

cc: Jim Connolly, Eastern Regional States Representative, National Association for Methadone Advocates
Peter Pennington, Executive Director, Pennsylvania Association of Methadone Providers
Gene Boyle, Director, PA Department of Health, Bureau of Drug and Alcohol Programs
Gerald Radke, Director, PA Department of Welfare, Office of Mental Health and Substance abuse Services
Kathy Hubert, Executive Director, PA Association of County Drug and Alcohol Administrators
Lynn Cooper, Senior Policy Specialist, PA Community Providers Association
Bob Waters, Executive Director, Magellan Behavioral Health of Pennsylvania
Michael Ratajczak, Executive Director, Aldie Foundation, Inc.
Mark Besden, Executive Director, Discovery House
Glen J. Cooper, Executive Director, New Directions Treatment Center, Inc.