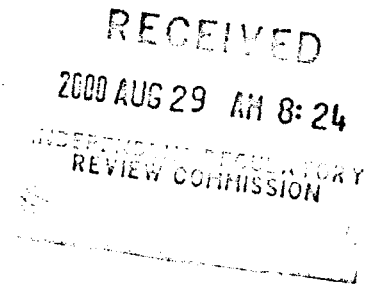




# Pennsylvania Association of Methadone Providers

July 26, 1999

Original: 2134



Bruce B. Douglas, C.A.S.  
President

Glen Cooper  
Vice President

Robert Holmes  
Treasurer

Lisa Murray  
Secretary

Robert Zimmerman, Secretary of Health  
P.A. Department of Health  
P.O. Box 90, Health and Welfare Building  
Harrisburg, PA 17108

Dear Secretary Zimmerman:

I'm writing on behalf of the Pennsylvania Association of Methadone Providers (P.A.M.P.). I have been coordinating the efforts of our Association in recent years to stimulate the reform of regulations pertaining to methadone treatment. We therefore commend your department for moving forward to revise and modernize regulation Chapter 263. Certainly, a number of genuine improvements have been put forth as embodied in the draft recommended to you by your quality assurance staff. However, our Association believes that there are other important changes which we had suggested which were not incorporated into the proposal. In order that we can all present a unified point of view to the Legislature and get new regulations promulgated in the least amount of time, we urge you to incorporate our positions, as discussed below, into your proposal. They include the following:

- Standard:** 263.3 Inspection for Approval  
**Discussion:** It is P.A.M.P.'s position that it is important to preserve an option for appeal comparable to that in the existing standard. We do not agree that an appeal need only be available in the case of denial or revocation of approval.
- Standard:** 263.9 Dispensing Staffing Pattern  
**Discussion:** Ratios should be one full-time person for every 300 patients in the case of automated systems and one for every 150 patients in the case of non-automated systems. It is felt that lesser ratios do not result in full utilization of staff and are, therefore, wasteful of resources. Additionally, P.A.M.P. believes that the proposed new language pertaining to persons being medicated in a "timely and orderly manner" is vague and unnecessary.
- Standard:** 263.10 Physician Staffing Pattern  
**Discussion:** The physician to patient ratio should be no less than one (1) physician hour per week for each 25 patients. It is P.A.M.P.'s position that ratios incorporating a smaller number of patients per physician hour are unnecessarily restrictive and a financial burden. We note that many states have no restrictions at all in terms of a physician/patient ratio. Regarding the language on qualifications of the Medical Director, we believe the sentence setting a time limit to meet credential requirements should be deleted. This is likely to cause major recruitment problems outside metropolitan areas. Finally, it is felt that the paragraph on use of PA/CRNP needs clarification and that PA/CRNP services should be supervised by any program physician not necessarily or only the Medical Director. Such limitation is unnecessarily restrictive and could be expected to interfere with patient care.

1810 Steelstone Rd.  
Allentown, PA 18103

E-mail: <http://www.worldvnx.net/prespamp>  
Website: <http://www.worldvnx.net/pamp>

4. **Standard:** 263.11 Psychosocial Services

**Discussion:** The proposed language under what would become 263.11 (b) pertaining to services being available via an “accessible provider” should be stricken. The term “accessible provider” is excessively vague and it may well be beyond the ability of the methadone program to entice an agency the Department would deem “accessible” into signing an agreement.

Concerning the service quantities referenced in what would become 263.11 (a): P.A.M.P. reiterates its earlier recommendations, specifically: 1) Each patient shall be provided an average of 2.5 hours of psychotherapy per month during their first year, 2) one hour of the minimum during the first year shall be individual psychotherapy, 3) after one year of maintenance treatment, an average of one hour of either group or individual psychotherapy per month shall be provided, and 4) after three years of maintenance treatment, six hours of psychotherapy shall be provided to each patient each year. It is felt that, commonly, patient need for medication outlasts the need for monthly psychotherapy. This is recognized in the federal initiative to move long stabilized patients into private physician office treatment.

5. **Standard:** 263.12 Psychosocial Staffing Patterns

**Discussion:** The standard under Chapter 263 is currently written as a ratio of at least one counselor/therapist to 40 patients receiving treatment. It is noteworthy that this is a different ratio than applies to treatment facilities under Chapter 704. There is, therefore, no impediment to enacting P.A.M.P.’s recommendation to increase the ratio to one counselor for each 50 patients (in recognition of longer-term patients needing less counseling and the greater use of group therapy). It is also P.A.M.P.’s position that parts of 263.12 be struck which prohibit the counting of hours of counselors simply because they work less than 15 hours per week/1/3 full-time. Such restriction unfairly holds methadone programs to a different standard than other outpatient programs regulated solely by Chapter 704.

6. **Standard:** 263.13 Intake

**Discussion:** P.A.M.P. members feel that the proposed language changes do not satisfactorily address readmission of persons formerly in treatment. It is our belief that, regardless of voluntary versus involuntary termination or number of years out of treatment, readmission be left entirely to the discretion of the program so long as current dependence is demonstrated.

7. **Standard:** 263.17 Termination

**Discussion:** Because the Department has, correctly or incorrectly, interpreted this section to mean nonpayment is not in itself grounds for termination, P.A.M.P. believes that “nonpayment of fees” should be specifically included in the list of conditions. Whether provided on a “nonprofit” or “for profit” basis, many methadone programs would quickly go out of business were patients to perceive that they could stop paying indefinitely without being terminated from services.

The above represents issues about which there is broad agreement among P.A.M.P. members.

We strongly urge you to address these points prior to sending the proposed revision further along in the approval process. We have tried as an Association to focus only on those issues deemed most important although individual programs have numerous additional matters of concern. This document is intentionally succinct and we would be pleased to meet with you to discuss any or all of these issues.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Glen Cooper", written in a cursive style.

Glen Cooper, Vice President



**PENNSYLVANIA COMMUNITY PROVIDERS ASSOCIATION**

2400 Park Drive • Harrisburg, PA 17110-9303

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2000 AUG 31 PM 2:09

INDEPENDENT REGULATORY  
REVIEW COMMISSION

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August 28, 2000

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John C. Hair, Director  
Bureau of Community Program Licensure and Certification  
Pennsylvania Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104

Dear Mr. Hair:

The purpose of this letter is to provide comments regarding the proposed regulations entitled Narcotic Addiction Treatment Standards in Chapter 715 on behalf of the members of the Pennsylvania Community Providers Association that provide methadone maintenance services.

**Regional Representatives**

**Central**  
Charles Hooker, III  
Scott Moyer, MSW, LSW  
Susan Noya  
Barry K. Wyrick  
**Northeastern**  
Frances Malley  
Daniel McGrory  
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William C. Folks, MSW, LSW  
Karen Graff  
William Parfitt  
**Western**  
Steve Christian-Michaels  
Chris Garrett, LSW  
Michael Quinn  
Kara Rutowski

1. PCPA members are committed to high quality care, but opposed to unnecessary, excessive, and costly regulations. The requirement for physician hours is unnecessary, excessive, and costly. Many states have no requirements in this area. Methadone program physicians across the state do not support this requirement.
2. PCPA members have long expressed opposition to the counselor/patient ratio for outpatient services in the staffing regulations. For methadone maintenance providers this requirement is even more inappropriate. Patients in these programs are typically more long-term and in need of less counseling and services over time.
3. It is our understanding that the department is opposed to the FDA definition of "medication unit." Providers must have an opportunity to provide satellite or mobile units to make medication services more accessible to clients. If medication units must be prohibited, then some alternative to make medication more accessible must be discussed and approved by the department.
4. The proposed regulations do not allow any opportunity for providers to appeal issues related to noncompliance, expansion, and/or capacity. The proposed regulations only address denial or revocation of approval. There must be a process in place for providers to appeal on other critical issues as listed above. Providers must also have another entity to appeal to rather than resubmitting their appeal to the same entity that initially gave a negative response.
5. We recommend that the term "chain of custody" be removed from section 715.14. This term is specific to one type of procedure and is expensive and unnecessary. We recommend that language that is more generic replace it such as "assure procedures, which would minimize the misidentification of urine specimens."
6. Section 715.28(c)(1) is important to protect patients, however, we recommend that the statement be simplified to state "Complaints of patient abuse." The examples provided are unnecessary.
7. If a client is determined to be required to pay for services, the provider must be able to terminate services for nonpayment in some cases. Providers work hard to assist clients to

**Honorary Board Members**

Marvin Batten  
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Cheryl Flanagan  
Melvin Haber  
Joseph H. Knecht, LSW, MHA  
Rex McClure, Ph.D.  
Colleen McGuigan

**Executive Director**

George J. Kimes

*"PCPA promotes a community-based, responsive and viable system of agencies providing quality services for individuals receiving mental health, mental retardation, addictive disease and other related human services"*

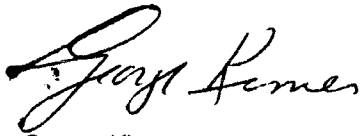
access available funding to support their services and to assist patients, as a part of rehabilitation, to work to support themselves. However, methadone providers would not be able to remain in business if they were not able to require payment from those deemed liable for their services.

8. We recommend that only non-clinical issues directly and specifically involving the program director be required to be heard by the governing board. There are many instances in which the governing body of a non-profit corporation would not be appropriate to hear grievances of patients, for example, large hospitals or parent organizations with boards of trustees or no direct involvement in clinic affairs.

Thank you for the opportunity to comment on these regulations. We look forward to continuing to work with you as they are finalized and are hopeful that the department and treatment providers can reach agreement in areas where disagreement exists.

If you have any questions please contact Lynn Cooper of my staff.

Sincerely,

A handwritten signature in black ink that reads "George Kimes". The signature is written in a cursive style with a large, sweeping initial "G".

George Kimes  
Executive Director



Thomas Jefferson  
University

Jefferson  
Medical  
College

Department of Psychiatry  
and Human Behavior

1201 Chestnut Street  
Philadelphia, PA 19107-4192

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ORIGINAL: 2134  
August 28, 2000

INDEPENDENT REGULATORY  
REVIEW COMMISSION

John C. Hair  
Director, Bureau of Community Program  
Licensing and Certification  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104

Dear Mr. Hair:

I would like to take this opportunity to express my comments and objections to the proposed regulations related to narcotic treatment as published in the July 29, 2000 Pennsylvania Bulletin.

As you know, I have been the medical director of the Narcotic Addict Rehabilitation Program (NARP) of Thomas Jefferson University for the past 12 years. In addition to being a fellow of the American Society of Addiction Medicine (ASAM), I am a board certified addiction psychiatrist and am certified, by examination, in addiction medicine by ASAM. At Jefferson, I am an associate professor of psychiatry and human behavior. Nationally, I am a member of the opioid maintenance pharmacotherapy committee of ASAM and have helped develop and teach the 'Methadone Treatment Program Course for Clinicians' that has been offered by the American Methadone Treatment Association (AMTA). It is through this involvement with the provision of narcotic addiction treatment services that I feel both the need to and qualified to comment and object to some of the guidelines proposed in the above mentioned issue of the Pennsylvania Bulletin.

In general, the proposed regulations are much needed and will bring the regulations in touch with current state of the art practice. However, a few guidelines I believe are out of step.

#### § 715.6 Physician Staffing

(2) "The interim medical director shall meet the qualifications within 24 months of being hired."

This is an unreasonable time limit. Examinations by ASAM are held roughly every 2 years. In order to sit for the exam a physician must document a one year FTE experience in addiction medicine. The certification process for added qualification in addiction psychiatry by the American Board of Psychiatry and Neurology is similar. For many NTPs, physicians are recruited from the community and they may not have sufficient time dedicated in the field to be able to comply with this regulation and sit for the exam in the allowed 24 months. A training program documenting specific education in addiction and narcotic treatment should suffice to guarantee that the NTP has a current and up-to-date practitioner. This will also allow communities where treatment services are necessary to develop and implement programs to meet their needs.

(d) "Narcotic treatment programs shall provide physician services at least 1 hour per week onsite for every ten patients."

John C. Hair  
Page 2

This is an unreasonable number of hours. Relaxation to 1 hour of physician time per week for every 15 patients would suffice to meet both patient and program needs. Setting this ratio too high places an unnecessary barrier to smaller program to be able to attract and pay for medical services.

(f) "Two hours of physician assistant or certified registered nurse practitioner time shall be equivalent to one hour of physician time."

This is absurd. PAs and NPs are very well suited to provide medical services in a NTP. Such services are focused and specialized such that a PA or NP could master many of the skills necessary to become an invaluable treatment team member. In addition, they have physicians available for consultation for more complicated issues. There is no need to count their time as half of a physician counterpart because the work that is performed requires the same time whether done by a physician, PA or NP.

#### § 715.14 Urine testing

(c) "A narcotic treatment program shall develop and implement policies and procedures addressing chain of custody of a urine specimen to ensure that the tested specimen can be traced to the person to whom it belongs."

This is unnecessary and overly and unduly burdensome. Usual laboratory labeling practice accurately assures this for the type of urine testing that is used in NTPs. Chain of custody is indicated and used in situations where the results of the urine drug test could result in loss of a job, or criminal proceedings. This section [section (c)] should be deleted.

#### § 715.15 Medication dosage

(c) and (e) "...formulations may be distributed by the program, all oral medications required to be administered or dispensed in a liquid form."

Shouldn't this be distributed to the program rather than by? The program receives the material then dispenses it.

Thank you for allowing me to comment on the proposed regulations. Please feel free to contact me with questions about my comment or if I can be of help in any regard with the regulations.

Sincerely,

Peter A. DeMaria, D., M.D., FASAM  
Medical Director, Jefferson NARP  
Associate Professor of Psychiatry  
And Human Behavior



## BUCKS COUNTY DRUG &amp; ALCOHOL COMMISSION, INC.

600 Louis Drive, Suite 102-A, Warminster, PA 18974  
 (215) 773-9313, Fax: (215) 956-9939  
 email: [beda@mail.comcat.com](mailto:beda@mail.comcat.com)

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INDEPENDENT REGULATORY  
REVIEW COMMISSION

August 28, 2000

John Hair, Director  
 Bureau of Community Program Licensure and Certification  
 132 Kline Plaza, Suite A  
 Harrisburg, PA 17102

Dear John:

We have reviewed the proposed amendments to treatment standards for the narcotic addiction treatment program. We have also reviewed the concerns and suggestions as submitted by the Pennsylvania Association of Methadone Providers (PAMP). We support the position of PAMP with respect to the thirteen items they present. Our comments are to be considered as supplemental to their items. We respectfully request that you consider our concerns and/or questions as enclosed in this document.

1. We do feel that there needs to be a distinction made in addressing the pharmacotherapy needs of long-term clients versus clients in the first few years of a program of methadone maintenance. We are hoping to see regulations in Pennsylvania that will support a movement to physician dispensing of methadone in a medical setting, i.e. the New York Mt. Sinai model. The question we have is will the proposed regulations in any way impede growth in this direction? Or will this aspect of pharmacotherapy not come under the classification of "treatment programs"?

We would guess that physicians would ideally like to be free to prescribe methadone as any other medication, but we certainly understand a position that would place some limits in this area. If all methadone dispensing is seen to come under the proposed regulations, then we strongly believe that the proposed regulations should in some way distinguish between the long-term maintenance clients and other clients and not close the door for the option of physician dispensed methadone. We suggest the line be drawn as to length of treatment and other factors for consideration for physician dispensing, based on the results of the recent research in this area. If physician dispensed methadone will be addressed through another regulatory process, what will this process be and when can we expect to see these developed?

2. (Reference 715.6, Secretary Zimmerman 7/26/00 letter, 715.8, 715.18, 715.19) We agree that there is a need for allowing for a different treatment approach for long-term

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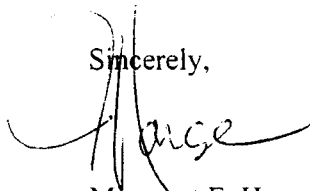


patients, as outlined in our response above. For those clients treated within a clinic setting we recommend that the Department acknowledge the different treatment needs and goals for long-term clients, particularly as to client ratio requirements, required physician hours, rehabilitative and psychotherapy services.

3. Can these proposed regulations provide a vehicle for listing exceptions to Pennsylvania confidentiality regulations? If so, then we should use this vehicle to support an expansion of what information can be released with client permission.
4. We are still hampered in this state in the delivery of methadone to clients in settings other than the methadone clinic, even when the dosing agency is the licensed methadone clinic. The current process of regulatory change provides an opportunity to support the delivery of methadone to clients in other settings to include other levels of care at a different licensed mental health and/or drug and alcohol treatment facility. The ability to provide this service is certainly state-of-the-art treatment and supported at both the federal and state (BDAP) levels. Acknowledgment of this possibility, if not goal, and the options and process for arranging for this to occur needs to be stated in the regulations.

In summary, the proposed regulatory language states that the purpose is to reflect updates in federal regulations and to “incorporate current treatment practices for narcotic addicts”. This process is an excellent opportunity to set the stage for further modification of the use of pharmacotherapy to address the treatment of narcotic addicts outside of the traditional clinic setting. Most certainly it can and should also expand the scope of treatment within the clinic setting for long-term clients/patients. Please let us know if you have any questions regarding our recommendations. We appreciate this opportunity to comment.

Sincerely,



Margaret E. Hanna  
Executive Director

cc: Gene Boyle, Director, BDAP  
Kathy Hubert, Executive Director, PACDAA

**MONTGOMERY  
COUNTY  
METHADONE  
CENTER**

316 DEKALB STREET/NORRISTOWN, PENNSYLVANIA/19401-4906

610-272-3710

Fax 610-270-0760

August 25, 2000

RE: Proposed amendments to treatment standards

John C. Hair

Director

Bureau of Community Program Licensure and Certification

132 Kline Plaza, Suite A

Harrisburg PA 17104

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PROFESSIONAL REGULATION  
REVIEW COMMISSION

Dear John C. Hair,

The following are the recommendations (as outlined by S. A. Warren, MD, Medical Director, Montgomery County Methadone Center) for clarification of the proposed amendments to treatment standards.

715.6 (e) – Delete

715.6 (f) – Delete

715.7 (a) (1) & (2) – Automated dispensing systems should require 1 full-time authorized dispensing person for every 100 patients.

715.8 – Explicitly state client/counselor ratio from Chapter 704

715.15 (c) – Delete the words “tablets, syrup concentrate or”

(e) – Delete the words “syrup concentrate or”

715.16 (d) (3) – Explicitly state that travel is one of the “exceptional circumstances”

715.17 (c) (1) (iii) – Explicitly permit staff in the dispensing area

715.21 (1) – Explicitly state that nonpayment can be grounds for termination through detoxification of not less than 21 days

715.22 (b) Explicitly define “governing body” and specify an appeal procedure to the highest level in the Division of Drug and Alcohol Programs

715.24 (4) (i) - Change “7 days per week” to “daily” to accommodate for 6 day opening

715.28 (4) – Clarify language and specify “incidents”

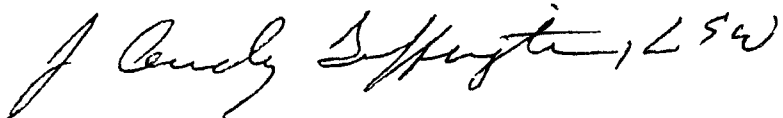
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Fax 610-270-0760

715.28 (5) – Specify circumstances of “drug related”

A handwritten signature in black ink that reads "J. Andy Buffington, L.S.W." The signature is written in a cursive style.

J. Andy Buffington, L.S.W.

Clinical Supervisor  
Montgomery County Methadone Center



formerly PBA, Inc., The Second Step

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REGULATORY REVIEW COMMISSION

August 25, 2000

John C. Hair, Director
Bureau of Community Program
Licensure and Certification
Pennsylvania Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104

Dear John:

Please accept this letter as our endorsement of the recommendations the Pennsylvania Association of Methadone Providers (PAMP) has forwarded to you relative to the proposed Rule Making, Chapter 715.

It is important to underscore how some of these proposed standards (i.e. Doctor's hours and client to counselor ratio's) are ostensibly "unfunded mandates" that weight very heavily on the finances of our program.

Secondly, we have some concerns about the licensing process itself. The ambiguities, uncertainties, changing definitions and inconsistencies that confront providers year to year, leads one to question the integrity of the current licensing process.

It does not appear that any consideration was given to the many systemic changes proposed by the Federal Government, such as accreditation and Physician Based Practices.

In closing, we hope that the recommendations forwarded to you will receive consideration, and where appropriate, be incorporated into Chapter 715 as it proceeds through the regulatory process.

Sincerely,

[Handwritten signature of Bruce B. Douglas]
Bruce B. Douglas, CAS
President/CEO

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National Association of Alcoholism and Drug Abuse Counselors, Drug & Alcohol Testing Industry Association



## Pennsylvania Association of Methadone Provide

Bruce B. Douglas, CAS  
President

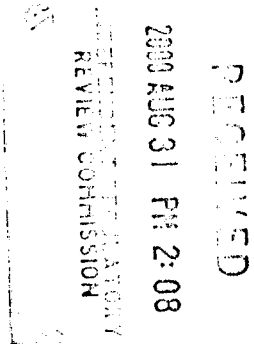
August 25, 2000

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Vie President

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Lisa Murray  
Secretary

John C. Hair, Director  
Bureau of Community Program  
Licensure and Certification  
Pennsylvania Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104



Dear Mr. Hair:

I'm writing to present comments on behalf of the Pennsylvania Association of Methadone Providers (P.A.M.P.) on proposed methadone regulations Chapter 715. P.A.M.P. has for several years advocated for the need to update existing regulations Chapter 263, and last year submitted to the Department what we felt were appropriate changes to that chapter. We also had earlier submitted comments on "Chapter 717" which were Licensing's original (if unofficial) draft of methadone regulations meant to replace Chapter 263. While we recognize that in promulgating proposed Chapter 715 the Department has made some of the changes favored by the regulated community, members definitely do not support a significant number of aspects of the chapter as is currently configured. For ease of reference, these comments are enumerated below. They are stated in an intentionally succinct manner. We would be please to elaborate in any hearings or other discussions, which may take place as the regulatory process moves forward.

1. Much of the language is overly prescriptive and should be replaced with "best practice" guidelines to accompany a more basic regulatory package.
2. The physician hour's requirement is excessive. Also, the aspect of needing two PA/CRNP hours to equal one-physician hours is contrived and unnecessary. (Reference 715.6 and 7/26/99 letter to Secretary Zimmerman)

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John C. Hair, Director  
Bureau of Community Program  
Licensure and Certification  
Pennsylvania Department of Health  
August 25, 2000, Page 2

3. Counseling service levels are fundamentally different in methadone treatment than in other outpatient treatment facilities in that fully rehabilitated patients often need to continue methadone therapy. Counselor staffing requirements should be more liberal in recognition that long term rehabilitated patients need and get reduced counseling. We are recommending a counselor to client ration of 1:50. (Reference 715.19 and 7/26/99 letter to Secretary Zimmerman)
4. Prohibition of medication units is not appropriate. (Reference 715.25) Recommendation of collaborative effort between dispensing unit and counseling center.
5. There is a need to retain an appeals mechanism for noncompliance as provided in current Chapter 263. We are recommending that the Director of Community Licensure and Certification hear appeals.
6. Establishing a "chain of custody" for urine specimens could result in major cost increases and is unnecessary in a medical services setting. (Reference 715.14) Recommend language "insure procedure which would minimize identification of urine".
7. The proposal is not in synchrony with federal regulatory reform efforts centering around 1) medical maintenance, and 2) JACHO/CARF accreditation.
8. There needs to be a more open and accountable process regarding program expansion including an appeals mechanism. (Reference 715.5)
9. The proposed requirement that we report to the Department any patient complaints of "financial, verbal, or emotional abuse" is not reasonable nor are these terms defined. (Reference 715.28).
10. Nonpayment should be included as a justification for termination (Reference 715.21).

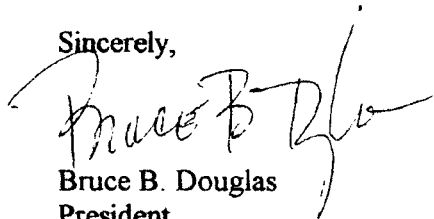
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John C. Hair, Director  
Bureau of Community Program  
Licensure and Certification  
Pennsylvania Department of Health  
August 25, 2000, Page 3

11. Patient grievance procedures would require grievances against the program director to be heard by the governing body. This is not realistic and volunteer Board members general do not have expertise in behavioral health. (Reference 715.22)
12. This regulatory opportunity should be used to incorporate a provision such that a patient can permit a provider to disclose any confidential information as the patient deems in his/her interest.
13. Language making reference to a given dosage as being either "high" or "low" should be removed.

Thank you for the opportunity to make comments on proposed Chapter 715. Methadone treatment providers look forward to working within the regulatory process to produce a set of regulations, which serve the needs of our patients and do not unreasonably burden the health care facilities, which provide these important services.

Sincerely,



Bruce B. Douglas  
President

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Pittsburgh, PA 15233  
412-322-8415

E-mail: <http://www.worldlynx.net/prespamp>  
Website: <http://www.worldlynx.net/pamp>

J. Michael Miroballi  
303 Coral Street,  
Lancaster, PA 17603

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REGULATORY  
REVIEW COMMISSION

Mr. John Hair, Director,  
Bureau of Community Program and Certification,  
132 Kline Plaza, Suite A,  
Harrisburg, PA 17104

25<sup>th</sup> August, 2000

Dear Mr. Hair,

I am writing to comment on the proposed changes to Methadone regulations in Pennsylvania. My wife and I have been receiving Methadone maintenance treatment since 1997 and I object to the following proposed regulations:

\* 715.25 Prohibition of medication units.

My wife and I have to travel 69 miles to receive onsite medication. The county in which we live does not have a methadone clinic. As parents of a young child and working full time close to my home, having to drive to the clinic is a burden which could be alleviated by having a medication unit closer to my home. This was especially difficult for my family in the early part of treatment when we had not yet stabilized enough to earn take home privileges.

• 715.14 Urine testing

The proposed reduction in testing requirements to once a month is not in the clients' best interest. In the early months of treatment or during a relapse, frequent screening helps clients achieve abstinence. It helps identify those who are in need of additional support. Denial, shame and guilt often prevent chemically dependent persons from acknowledging that they are using and without adequate screening, those most in need would not get the additional help they need.

I came to treatment to achieve and maintain abstinence and I do not wish to be exposed to others who are not interested in abstinence, who come to the clinic high, who are seeking drugs or offering drugs to other clients. An appropriate testing schedule, based on time in treatment and treatment status is essential to the success of any chemical dependency treatment and would eventually remove from treatment those who are not interested in being rehabilitated.

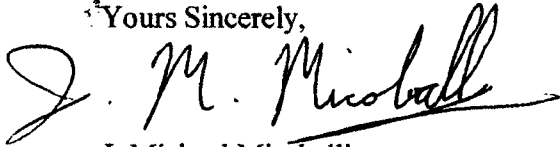


Inadequate monitoring of drug use in MMT clinics allows clients in treatment to continue to use opiates and other drugs. This has enhanced the public perception that methadone maintenance is not "real" treatment and continues to stigmatize those who use it.

- 715.6 and 715.8 Staffing Requirements

Until physicians are allowed to prescribe methadone for stable clients (which will reduce the cost of treatment for long term opiate dependent clients), I will have to continue to receive my medication through a Methadone Maintenance clinic. The proposed staffing requirements add significantly to the cost of treatment, are wasteful and unnecessary for a large number of clients in treatment like myself, who have achieved long term abstinence and stability in all aspects of our lives.

Yours Sincerely,

A handwritten signature in black ink, reading "J. M. Miroballi". The signature is written in a cursive style with a long horizontal flourish extending to the right.

J. Michael Miroballi

**Hair, John**

---

**From:** Hollins, Marilyn  
**Sent:** Friday, August 25, 2000 11:55 AM  
**To:** Hair, John  
**Subject:** FW: Comments to the Proposed Amendments to Treatment Standard for the Approval of Narcotic Addiction Treatment Programs

-----Original Message-----

**From:** Hollins, Marilyn  
**Sent:** Friday, August 25, 2000 11:40 AM  
**To:** Hair, John  
**Cc:** Hollins, Marilyn  
**Subject:** Comments to the Proposed Amendments to Treatment Standard for the Approval of Narcotic Addiction Treatment Programs

John,

I reviewed the proposed regulations for Narcotic Addiction Treatment Programs and was very impressed. I just have a few comments/questions.

715.10 Pregnant patients. This area should include a statement concerning informed risks to the pregnant woman or to her unborn child from continued use of illicit drugs and from the use of or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment. (Refer to FDA Regulations- 291.505, (B)(5))

715.12 Informed patient consent. This is not clear. Should the consent be the federal consent required from FDA, which may become obsolete? Should the consent be in writing and required to be signed by the patient? Should the consent specify that a narcotic drug such as methadone and/or Levo-Alpha-Acetyl-Methadol (LAAM) will be administered? Should the consent indicate if the female is pregnant or not?

715.17(c)(1)(iii) Administration of medication. When it states that on patients are permitted in the dispensing area, does this exclude staff? Or, do you mean that friends and family are not allowed?

715.17(c)(2) Drug storage area. There is some discretion needed for inpatient program that cannot access the safe during off-hours and need to keep a small supplies in a secure area (i.e. double locked box) for emergency use. DEA regulations (1301.72(1)) indicates where small quantities permit, a safe or steel cabinet;... Also, 1301.74(l) indicates that DEA may exercise discretion regarding the degree of security required in narcotic treatment programs...

715.23(b)(15) Patient records. Although, psychosocial evaluations has been added, the way it is written implies that the psychiatric, and psychological can replace it as a requirement. The psychosocial evaluation should be a separate item.

Thanks, John, for the opportunity to respond.

Marilyn

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2000 AUG 31 PM 2:08  
REVIEW COMMISSION

# DISCOVERY HOUSE

THE CENTER FOR RECOVERY & HOPE RECEIVED

2000 AUG 31 PM 2: 08

INDEPENDENT REGULATORY  
REVIEW COMMISSION

August 25, 2000

John C. Hari, Director  
Bureau of Community Program  
Licensure and Certification  
Pennsylvania Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104

Dear Mr. Hair:

Discovery House is writing to make comments on methadone regulation chapter 715, which has been published as proposed regulations. Discovery House agrees with your departments' initiative to bring the current regulation into the 21<sup>st</sup> century of treatment. Regulations, which should set the ground, work for Discovery House and our colleagues throughout Pennsylvania, to provide effective, high quality and access free treatment.

Discovery House also agrees with what is stated in the proposed regulation, under the purpose section, last paragraph, we quote "Existing regulations applied are not consistent with the current health practices or Federal requirements. They are more burdensome than the Federal regulation". We strongly agree with this statement, however the new proposed regulations are missing significant language that would truly modernize the proposed regulations. I would also suggest a terminology change from regulation (rulemaking) to "Best Practice Guidelines". This would send a message to the filed of a partnership and a common goal between the providers and the department of Drug and Alcohol. This language change would also set the ground work for the new regulation to be less prescriptive and more "best practice".

As is stated in the proposed regulation, this filed has changed.

I am convinced that you and your department have listen to the field's recommendation, because each of the definition stated in the proposed regulation highlight our concerns. Discovery House comments is as follows;

### 715.5 patient capacity

We have sent letters and had several discussions regarding our concern around this regulation. The way the language reads, regardless if we are fully licensed and fully staff, with sufficient space, we still need the state approval to admit patients. Discovery Houses experience in some cases has been weeks and months before we get approval to admit patients. In the mean time motivate patients are put on a waiting list with no treatment, and potential exposure to; HIV, Hepatitis, STD's and the need to continue with drug use and drug related practices.

### Our Mission

To provide comprehensive services for persons affected by addiction ~ through community awareness, quality and holistic clinic services ~ in efficient, safe and fiscally sound environment.

### Home Office

66 Pavilion Avenue • Providence, Rhode Island 02905 • (401) 785-4540 • Fax: (401) 785-8975  
1-888-DOORWAY • www.discoveryhouse.com

We believe the intent of this regulation is to protect the patient from those agencies, which operate in a provisional status and may require special attention from the department. However it has been our experience that even a clinic with 0 non-compliance still may wait months to get approval to treat additional patients.

Proposed language should read, "If a clinic can maintain a full license, correct staffing ratio as prescribe by the regulations and has the physical plant necessary to treat additional patient it should do so responsible and inform the state accordingly. The factors a clinic should consider include, Safety, Physical facility, staff size and composition, ability to provide required services, availability and accessibility of serves."

#### 715.8 psychosocial & 715.19 Psychotherapy services

As was detailed out in a document Discovery House presented to the department, we believe in keeping with the state requirement of individualized treatment, if the regulation needs to prescribe anything it should state a maximum a counselor can spend in direct care within a 40 hour work week.

Discovery House's interpretation of the current 704 regulation, the intent is that a counselor, not spend more than 50% of there time in director care and for a patient (lest than 2 year in treatment) not receive less than 2.5 hours of counseling. If this is true than clinical staff should be able to balance a caseload based on patient needed hours of treatment, not an arbitrary and capricious statement of 35 to 1 ratio.

The fact is if we don't allow clinics to excise there clinical approaches we will not stimulate competition and what follows competition is quality of care and lower cost to the consumer (patient).

If the regulation need to say anything it should realize that clinics hire counselor to counsel not do busy work to get 40 hours in per week. A counselor should spend 75% of their time in direct care and 25% with paperwork. This is another good example of the regulation being to prescriptive, something the HMO's have tried to do and failed miserably.

#### 715.6 Physician staffing

The physician to patient ratio should be no less than one (1) physician hour per week for each twenty-five (25) patients. It is further believed that the current ratio for a physician assistant and or nurse practitioner should be equivalent to that of physicians' ratio, with the understanding twenty percent (20%) or not less than 3 hours per week, of the medical time is provided by the physician.

Regarding the language on qualifications of the Medical Director, we believe the sentence setting a time limit to meet credentials requirements should be reviewed with the number of Medical Directors who are all ready credential. This type of language can have a dramatic effect on the access of treatment. If we look back at the 704 regulation, which set minimum requirement for counselors, no one took into account what the market would bear regarding available counselors. Presently we have a state wide shortage of approved counselors, clinical supervisory and program directors, and some of the people who have been denied have been providing these services for several years some have national credentials but still don't meet Pennsylvania's regulations.

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Discovery House like many of our colleagues want the best care possible for the patients, however access is just as important.

#### 715.9 Intake

The federal regulations are clear and complete when it comes to admissions, Discovery House suggests we default to these standards to insure we do not develop regulation, which create barriers to treatment.

The proposed regulations also do not address exception to minimum admission criteria, such as Penal or chronic care.

The re-admission criteria should also be modified to include any discharged patient, rather than only voluntary discharge.

#### 715.21 Patient Termination

Discovery House agrees that the clinic should make every effort possible to provide patient with due-process and withdraw form methadone not less than 7 days, our minimum is 10 days. However if the reason for the patients termination cause harm to the staff, other patients or the clinic existence, it is imperative that the program staff take all reasonable steps to direct the departing patient to appropriate treatment alternatives rather than set a minimum of 7 day detox. However if the program is not successful it should put the clinics staff and other patients safety first!

This section also list various bases on which programs may terminate treatment, Discovery House believes non-payment should be added to this list, particularly since the department has taken the position that non-payment itself is not permitted as justification for such termination.

Again it is imperative that the program staff take all reasonable steps to direct the departing patient to appropriate treatment alternatives.

#### 715.22 Patient Grievances

Discovery House has a detail grievance procedure which is critical to our continuous quality improvement. We agree with the importance of such a procedure, however we do not agree with the governing board's involvement. We believe a multi representative committee is a substitute for the governing board, given the distant involvement most boards have with day to day operations.

A second issue regarding grievance procedure is the language referring to the initiation of penalties. This language should be omitted from the proposed standards.

#### 715.23 Patient Records

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Discovery House like other facilities are completely computerized from admission to discharge. We would suggest that language be added to section (e); "Patient file records, information and documentation shall be legible, accurate, complete, written in English and maintained on standardized forms or standardized electronically and assessable by auditors."

Discovery House would like to remind the department that, the Center for Substance Abuse Treatment (CSAT) and Substance Abuse and Mental Health Services Administrations (SAMAHSA), has publish several documents that highlight best practices. Series worth reviewing "Approval and Monitoring of Narcotic Treatment Programs" and "State Methadone Treatment Guidelines"

We appreciate the opportunity to review and comment on these proposed regulation and believe that more collaboration between licensing and the agency's is imperative to the improved quality of care we provide to the opiate addicted patient of Pennsylvania. Additionally we would like to formally request a public hearing relating to this regulatory proposal and the appropriate point in the rule-making process.

Thank you for your consideration of these comments. If you have any question I have enclose my business card for your convenience.

Sincerely,



David L. Piccoli, II  
Vice President

Cc: Discovery House's Board of Directors  
Our 5 Discovery House's in Pennsylvania

#### Our Mission

To provide comprehensive services for persons affected by addiction ~ through community awareness, quality and holistic clinic services ~ in efficient, safe and fiscally sound environment.

**Hair, John**

---

**From:** Bashore, Carol  
**Sent:** Thursday, August 24, 2000 9:51 AM  
**To:** Hair, John  
**Cc:** Williams, Cheryl  
**Subject:** FW: methadone regulations

John - Looks like we need to change the wording in this proposed regulation, since our intent was that the program physician see the patient in order to appropriately make this determination. Suggested wording for 715.9 (4) - Include a determination by the narcotic treatment program physician, following an face to face assessment by this physician, that the person is currently physiologically dependent upon a narcotic drug and .... Cheryl - Any other thoughts on this wording ? Carol

-----Original Message-----

**From:** Ritchie, Theresa  
**Sent:** Thursday, August 24, 2000 9:31 AM  
**To:** Williams, Cheryl; Bashore, Carol  
**Subject:** methadone regulations

Section 715.9 (4) of methadone proposed regulations should be further clarified. The section states that prescribing methadone must "include a determination by the program physician that the individual is correctly physiologically dependent". The intent as well as the most appropriate care and diagnosis is achieved through an initial face to face determination between physician and patient; however, "determination" is not clearly defined. A third party consultation between a physician assistant, nurse practitioner, or other healthcare personnel and the physician without the physician ever physically seeing the patient could be construed as sufficient for "determination" of dependency. Therefore, "determination" should be further elaborated to ensure correct diagnosis and appropriate care.

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2000 AUG 31 PM 2:08  
STATE OF MISSISSIPPI  
REVIEW COMMISSION

# NEW DIRECTIONS Treatment Services

Original: 2134

August 23, 2000

John C. Hair, Director  
Bureau of Community Program  
Licensure and Certification  
Pennsylvania Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104

Dear Mr. Hair:

I am writing to make comments on methadone regulations Chapter 715 which have been published as proposed rule-making. New Directions Treatment Services is a nonprofit, charitable agency with two facilities in eastern Pennsylvania. We have been providing methadone services since 1980 and currently serve 430 patients. Our comments are as follows:

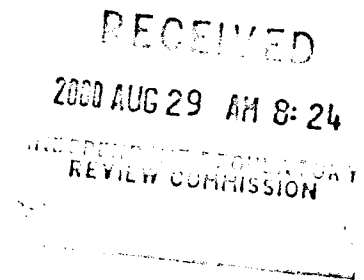
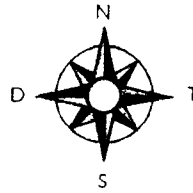
## General comments:

We believe that a relatively small number of changes in existing Chapter 263 regulations (along the lines of P.A.M.P.'s letter to Secretary Zimmerman dated July 26, 1999 - copy enclosed) would be the most appropriate way of addressing this issue. Proposed Chapter 715 represents a dramatic expansion in the size and scope of regulatory purview which is neither necessary nor appropriate. Much of this could be in the form of "best practices" guidelines accompanying a much-reduced regulatory package. We also feel that Chapter 715 has not adequately reflected the legitimate interests of the regulated community as they have been expressed on a number of occasions. In particular, the Department needs more input from medical professionals (only one of whom was invited to participate in a very large "stakeholders" group). Finally, I would question the Department's statement accompanying the proposed regulation that programs "will experience savings as a result of these proposed amendments." I believe the result may well be cost increases added to a current regulatory burden which forces many unnecessary costs onto programs and consumers. These costs create barriers to treatment.

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





Specific comments:

- Chapter 715 would continue the current policy of “micromanaging” programs by, among other things, specifying how many physician hours, nurse hours, counselor hours, and so on it takes to serve any given number of patients. Even more unfortunately, it would do so in a very liberal fashion, making it very difficult to operate a program that can remain solvent while receiving Medical Assistance rates or what lower income people can afford to pay out-of-pocket. This is a major reason for the dearth of programs in much of the State. Both current regulations and proposed Chapter 715 require 2.5 times as many physician hours as the recommendation of treatment providers. (Reference 715.6 and 7/26/99 letter to Secretary Zimmerman). Many states, including neighboring Ohio and New York, have no requirements at all on that subject. The Department has stated in writing that the basis for the physician hour requirement is that the patients need medical treatment for hepatitis, AIDS and other medical problems that have nothing to do with methadone treatment per se. However well intentioned, it is not appropriate to use methadone regulations to force programs into the role of general medical service providers and payment levels for our services certainly do not take that into account.
- In the same vein, the proposed regulations would reduce the counselor/patient ratio for methadone programs to the same level as non-methadone programs which typically don't treat long term, abstinent patients needing only reduced counseling services. (Reference 715.19 and 7/26/99 letter to Secretary Zimmerman). At our facility, the vast majority of patients are consistently free of any illicit drug use and the regulations clearly permit long term patients to get only monthly group counseling. It is often physically impossible to meet funder requirements that a counselor spend 60% of his time in face-to-face counseling with patients and at the same time for that counselor to not have more than 35 patients on their roster. While we understand the bias toward having such things be consistent for all drug and alcohol facilities, methadone is fundamentally different in terms of counseling services.
- The low regard which some persons have toward methadone treatment is largely related to the fact that many patients in treatment continue to use heroin and other addictive drugs. This problem is at the heart of why it's so hard to site new programs. There needs to be a greater regulatory emphasis on whether methadone patients stop using drugs. The proposed regulation, Chapter 715.14, does not set reasonable and appropriate standards for monitoring drug use via urine screening. The frequency of monthly screening is inadequate for patients in the early months of treatment or who have relapsed and the current requirement of weekly testing should be retained for all but the more stable patients. Further, the list of drugs

given in the proposal are not well chosen. The proposal needs to address these and other issues such as the use of plasma methadone levels, increased counseling for patients shown to be using illicit drugs, and so on if the regulations are really intended to define treatment standards. These additional costs can easily be paid out of savings realized by eliminating excessive staffing requirements as discussed above. Despite the extremely detailed nature of Chapter 715, it manages to largely avoid addressing genuine quality-of-treatment issues.

- The proposed regulation Chapter 715.25 would prohibit medication units as approved of by the FDA. Introductory materials provided with draft Chapter 715 imply that persons served by medication units would not receive comprehensive services. More correctly, such patients receive medication at one site typically convenient to their residences and travel a longer distance less often for counseling and other services. We have a number of patients traveling up to 120 miles round trip on a daily basis for services. This makes remaining in treatment very difficult and employment nearly impossible. We have been told by the licensing division that satellite dosing sites we had proposed would be turned down as they would constitute medication units. While medication units may not be absolutely ideal, in a state with limited treatment facilities such units are necessary.
- Chapter 715 regulations would delete the provision of existing Chapter 263 which provides a mechanism for appealing regulatory findings of noncompliance. Based on our experience, this government agency is prone to interpreting the meaning of regulations in ways that contradict the literal language. For example, I've been told on occasion that the word "may" is being interpreted as "shall" by the Division. We believe that an appeals process should definitely be included in Chapter 715.
- Proposed Chapter 715 offers many examples of regulatory overkill and intrusiveness into methadone treatment that would not be tolerated in any other area of health care. For example, section 715.28 (c) would quite reasonably require reporting of patient deaths, physical abuse or disruption of services. However, this subsection would also require reporting of any claim by a patient (even where the facility feels that such is completely without basis) of "financial abuse, verbal abuse or emotional abuse." This section needs to be revised to require reporting only of deaths, disruption of services, physical/sexual abuse, or similar incidents as would be normal in regulation of other health care facilities. Patients already have recourse to file complaints about quality of care issues with their County SCA's, the State, their attorneys, or they can simply seek services from another provider. Further, Section 715.22 requires patient grievances against the program director (often times the decision-maker) to be heard by the "governing body" of the agency. That is unworkable on a number of grounds and

I would challenge the Department to cite any other health care facility subject to such a regulation. Further, the program director is generally not the highest level staff person in the organization and volunteer board members often do not have behavioral health expertise. As noted above, patients do have other recourse. This provision possibly could be supported if it was limited to nonclinical matters where there is a claim of illegal activity, abuse, or similar allegation against the director.

- We believe that any revision in state methadone regulations should be consistent with the direction of the federal government in that regard. The federal government's FDA is in the process of ceasing its on-site inspections using federal regulations and FDA staff in favor of a detailed accreditation process under JACHO or CARF. These are private sector bodies that are highly respected in the health care field and are the primary overseers of quality issues in hospitals, home health agencies, and so on. Further, the accreditation standards developed by JACHO and CARF reflect the opinion of federal experts that outcomes and roles of staff should be emphasized over very prescriptive standards describing what must be in treatment plans, records, numbers of staff, and "micromanagement" so typical of past and current practices. Methadone treatment is a health care service and should be regulated in the same way other health care services are regulated. Likewise, the federal government proposes to allow long term, stabilized patients to be prescribed methadone by a competent private physician and recognizes that at some point the patient continues to need methadone medication but no longer needs counseling or to be physically observed taking the medication. We believe that the requirements for methadone clinics should be similar so that certain exceptional patients could be relieved of the need for counseling and urine screening as specified in the regulation. In such circumstances these matters would be left to the discretion of the program physician. It's not clear how Chapter 715 could ever be reconciled with such an approach. At a minimum, State regulations should be written in such a way as to not preclude this change in approach which is still being finalized at the federal level. Perhaps it would be best for State regulation to be left as it is until this very major change at the federal level is fully realized.
- A provision (i.e., Chapter 715.14) that programs must develop procedures for managing urine specimens uses the term "chain of custody." That term has a specific meaning which, if implemented in its usual, literal sense would increase our testing costs by about 400% (or \$250,000 per year). There is no need or precedent for requiring health care facilities to handle such specimens as forensic specimens. We recommend language simply stating that programs must develop procedures which would minimize the chance of misidentification of specimens.

- The provisions in Chapter 715.5 relating to program expansion of patient numbers needs to reflect a more open process and one with an appeal procedure. The ability to deny requests for program expansion is widely perceived as having been abused in the past by Bureau staff. It is not a power exercised by the Department over other health care facilities and its tremendous potential for abuse means it needs to be managed with great care and fairness.
- Section 715.2 lists various bases on which programs may terminate treatment of patients on an involuntary basis. We believe that list should include nonpayment of fees, particularly since the Department has taken the position that nonpayment itself is not permitted as a justification for such termination. In no other area of outpatient medical treatment would a provider be expected to continue services indefinitely even in the total absence of payment.

In summary, we believe it to be very important that a number of changes be made to proposed Chapter 715. The Department did not get sufficient input from medical persons and should pursue such input from all current methadone program medical directors and nursing supervisors. Indeed, a number of provisions of proposed Chapter 715 were never exposed to the regulated community for comment of any kind prior to their publication. We believe the regulations should be much more oriented to patient outcomes and much less oriented to dictating in minute detail how to achieve those outcomes.

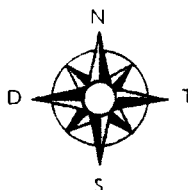
Thank you for your consideration of these comments. We request that a public hearing be held relating to this regulatory proposal at the appropriate point in the rule-making process.

Sincerely,



Glen Cooper  
Executive Director

# NEW DIRECTIONS Treatment Services



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2000 AUG 31 PM 2:08

INDEPENDENT REGULATORY  
REVIEW COMMISSION

August 23, 2000

John C. Hair, Director  
Bureau of Community Program  
Licensure and Certification  
Pennsylvania Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104

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Specific comments:

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- Proposed Chapter 715 offers many examples of regulatory overkill and intrusiveness into methadone treatment that would not be tolerated in any other area of health care. For example, section 715.28 (c) would quite reasonably require reporting of patient deaths, physical abuse or disruption of services. However, this subsection would also require reporting of any claim by a patient (even where the facility feels that such is completely without basis) of "financial abuse, verbal abuse or emotional abuse." This section needs to be revised to require reporting only of deaths, disruption of services, physical/sexual abuse, or similar incidents as would be normal in regulation of other health care facilities. Patients already have recourse to file complaints about quality of care issues with their County SCA's, the State, their attorneys, or they can simply seek services from another provider. Further, Section 715.22 requires patient grievances against the program director (often times the decision-maker) to be heard by the "governing body" of the agency. That is unworkable on a number of grounds and

I would challenge the Department to cite any other health care facility subject to such a regulation. Further, the program director is generally not the highest level staff person in the organization and volunteer board members often do not have behavioral health expertise. As noted above, patients do have other recourse. This provision possibly could be supported if it was limited to nonclinical matters where there is a claim of illegal activity, abuse, or similar allegation against the director.

- We believe that any revision in state methadone regulations should be consistent with the direction of the federal government in that regard. The federal government's FDA is in the process of ceasing its on-site inspections using federal regulations and FDA staff in favor of a detailed accreditation process under JACHO or CARF. These are private sector bodies that are highly respected in the health care field and are the primary overseers of quality issues in hospitals, home health agencies, and so on. Further, the accreditation standards developed by JACHO and CARF reflect the opinion of federal experts that outcomes and roles of staff should be emphasized over very prescriptive standards describing what must be in treatment plans, records, numbers of staff, and "micromanagement" so typical of past and current practices. Methadone treatment is a health care service and should be regulated in the same way other health care services are regulated. Likewise, the federal government proposes to allow long term, stabilized patients to be prescribed methadone by a competent private physician and recognizes that at some point the patient continues to need methadone medication but no longer needs counseling or to be physically observed taking the medication. We believe that the requirements for methadone clinics should be similar so that certain exceptional patients could be relieved of the need for counseling and urine screening as specified in the regulation. In such circumstances these matters would be left to the discretion of the program physician. It's not clear how Chapter 715 could ever be reconciled with such an approach. At a minimum, State regulations should be written in such a way as to not preclude this change in approach which is still being finalized at the federal level. Perhaps it would be best for State regulation to be left as it is until this very major change at the federal level is fully realized.
- A provision (i.e., Chapter 715.14) that programs must develop procedures for managing urine specimens uses the term "chain of custody." That term has a specific meaning which, if implemented in its usual, literal sense would increase our testing costs by about 400% (or \$250,000 per year). There is no need or precedent for requiring health care facilities to handle such specimens as forensic specimens. We recommend language simply stating that programs must develop procedures which would minimize the chance of misidentification of specimens.



- The provisions in Chapter 715.5 relating to program expansion of patient numbers needs to reflect a more open process and one with an appeal procedure. The ability to deny requests for program expansion is widely perceived as having been abused in the past by Bureau staff. It is not a power exercised by the Department over other health care facilities and its tremendous potential for abuse means it needs to be managed with great care and fairness.
- Section 715.2 lists various bases on which programs may terminate treatment of patients on an involuntary basis. We believe that list should include nonpayment of fees, particularly since the Department has taken the position that nonpayment itself is not permitted as a justification for such termination. In no other area of outpatient medical treatment would a provider be expected to continue services indefinitely even in the total absence of payment.

In summary, we believe it to be very important that a number of changes be made to proposed Chapter 715. The Department did not get sufficient input from medical persons and should pursue such input from all current methadone program medical directors and nursing supervisors. Indeed, a number of provisions of proposed Chapter 715 were never exposed to the regulated community for comment of any kind prior to their publication. We believe the regulations should be much more oriented to patient outcomes and much less oriented to dictating in minute detail how to achieve those outcomes.

Thank you for your consideration of these comments. We request that a public hearing be held relating to this regulatory proposal at the appropriate point in the rule-making process.

Sincerely,



Glen Cooper  
Executive Director



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LABORATORY  
REVIEW COMMISSION

August 23, 2000

John C. Hair, Director  
Bureau of Community Program Licensure  
and Certification  
Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104

Dear Mr. Hair;

I am responding to Proposed Rules, Chapter 715 concerning regulation of narcotic addiction treatment.

My comments are as follows:

**§ 715.6 Physician staffing.**

**(2) Physician training...**

*The provision for a training plan for an interim medical director achieving competencies and minimum qualifications allows for insufficient time for a physician to become qualified. ASAM, for example, generally provides testing only every other year. Thus, depending on a physician's start date, it may be impossible to meet the standard. I suggest that interim medical directors be provided 36 months to achieve minimum qualifications.*

**(3) (d) ...provide physician services at least 1 hour per week onsite for every ten patients.**

*It is my professional opinion that this standard is excessive and will seriously threaten survival of smaller clinics. The economics of narcotics addiction treatment for smaller clinics simply doesn't allow for such a large and unnecessary allocation to physician services.*

*I would like to point out that the consensus of the stakeholders group is not reflected in these physician regulations. As previously communicated, I left the meeting believing that we reached consensus at a ratio of 1 to 15.*

*Forcing this level of physician attendance is not medically or clinically necessary, is wasteful of resources, and will make it extremely difficult for small independent providers to hire physician services.*

Mr. John Hair  
August 23, 2000  
Page Two

(e) ...two-thirds of required physician time.

*Regulation of Advanced Practice Nurses and Physician Assistants is already accomplished through licensure and delegation agreements approved by other regulators in the state. It is not reasonable for the Department to impose these additional regulations which effectively serve to increase costs without corresponding benefit.*

(f) APN's and PA's

*It is equally unreasonable for the Department to force additional regulations on practitioner's regulated and licensed by other Departments. There is not one other medical specialty that limits the practice of APN's or Physician's Assistants in this fashion. An hour of service from these licensed health care providers should be fully considered as it is in physician offices, emergency rooms, and other medical facilities.*

§ 715.16 Take-home privileges

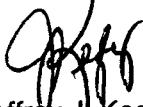
*I am concerned that the impending approval for office-based physician's to prescribe buprenorphine coupled with trends toward "medical maintenance" (allowing patients with substantial time and compliance in the clinic system to have as many as 30-days of take home medication) will seriously impact the clinic system in the Commonwealth. I further believe that clinics must respond to these changes by allowing "senior" patients to remain in clinics and be able to receive up to 30-days of medication.*

*The proposed regulations seem to allow for an exception to be granted for such patients allowing them to attend a clinic twice monthly and receive a two week supply of medication. However, there is no clear procedure for how these requests will be approved or by whom. Will a physician make these determinations?*

*I strongly suggest that recent developments indicate a need to revisit these regulations and provide clear guidelines for medical management of patients who have substantial "clean" time with 5 or more years in treatment. I suggested that guidelines provided in the current Federal Waiver for programs seeking accreditation be reviewed and considered for inclusion in this section.*

I would be happy to discuss my comments with you in more detail should you wish. Please feel free to contact me at (877) 620-6077.

Sincerely,



Jeffrey J. Kegley  
Executive Vice President



# Council on Chemical Abuse

Concilio de Abuso de Sustancias Químicas

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BERKS COUNTY LABORATORY  
REVIEW COMMISSION

August 22, 2000

Mr. John C. Hair, Director  
Bureau of Community Program Licensing  
and Certification  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104

Dear Mr. Hair:

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 though they require very little monitoring by a counselor. While these long-term clients require monitoring, we believe they do not need the oversight of a qualified therapist. Therefore, we

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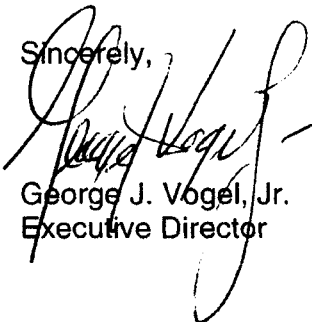
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suggest that clients who, after a two-year period, no longer need regular counseling either not be counted towards the client/counselor ratio or be counted as some percentage of a client.

Finally, we believe that clients in the early stages of narcotic addiction treatment should be required to undergo more frequent urine drug testing than once 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

DATA/PAPA-S/Letter Hair Methadone.doc

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



ORIGINAL: 2134

## Pennsylvania Association of Methadone Providers

July 26, 1999

Robert Zimmerman, Secretary of Health  
P.A. Department of Health  
P.O. Box 90, Health and Welfare Building  
Harrisburg, PA 17108

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REVIEW COMMISSION

Bruce B. Douglas, C.A.S.  
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Dear Secretary Zimmerman:

I'm writing on behalf of the Pennsylvania Association of Methadone Providers (P.A.M.P.). I have been coordinating the efforts of our Association in recent years to stimulate the reform of regulations pertaining to methadone treatment. We therefore commend your department for moving forward to revise and modernize regulation Chapter 263. Certainly, a number of genuine improvements have been put forth as embodied in the draft recommended to you by your quality assurance staff. However, our Association believes that there are other important changes which we had suggested which were not incorporated into the proposal. In order that we can all present a unified point of view to the Legislature and get new regulations promulgated in the least amount of time, we urge you to incorporate our positions, as discussed below, into your proposal. They include the following:

- Standard:** 263.3 Inspection for Approval  
**Discussion:** It is P.A.M.P.'s position that it is important to preserve an option for appeal comparable to that in the existing standard. We do not agree that an appeal need only be available in the case of denial or revocation of approval.
- Standard:** 263.9 Dispensing Staffing Pattern  
**Discussion:** Ratios should be one full-time person for every 300 patients in the case of automated systems and one for every 150 patients in the case of non-automated systems. It is felt that lesser ratios do not result in full utilization of staff and are, therefore, wasteful of resources. Additionally, P.A.M.P. believes that the proposed new language pertaining to persons being medicated in a "timely and orderly manner" is vague and unnecessary.
- Standard:** 263.10 Physician Staffing Pattern  
**Discussion:** The physician to patient ratio should be no less than one (1) physician hour per week for each 25 patients. It is P.A.M.P.'s position that ratios incorporating a smaller number of patients per physician hour are unnecessarily restrictive and a financial burden. We note that many states have no restrictions at all in terms of a physician/patient ratio. Regarding the language on qualifications of the Medical Director, we believe the sentence setting a time limit to meet credential requirements should be deleted. This is likely to cause major recruitment problems outside metropolitan areas. Finally, it is felt that the paragraph on use of PA/CRNP needs clarification and that PA/CRNP services should be supervised by any program physician not necessarily or only the Medical Director. Such limitation is unnecessarily restrictive and could be expected to interfere with patient care.

1810 Steelstone Rd.  
Allentown, PA 18103

E-mail: <http://www.worldvnx.net/prespamp>  
Website: <http://www.worldvnx.net/pamp>

4. **Standard:** 263.11 Psychosocial Services  
**Discussion:** The proposed language under what would become 263.11 (b) pertaining to services being available via an "accessible provider" should be stricken. The term "accessible provider" is excessively vague and it may well be beyond the ability of the methadone program to entice an agency the Department would deem "accessible" into signing an agreement.
- Concerning the service quantities referenced in what would become 263.11 (a): P.A.M.P. reiterates its earlier recommendations, specifically: 1) Each patient shall be provided an average of 2.5 hours of psychotherapy per month during their first year, 2) one hour of the minimum during the first year shall be individual psychotherapy, 3) after one year of maintenance treatment, an average of one hour of either group or individual psychotherapy per month shall be provided, and 4) after three years of maintenance treatment, six hours of psychotherapy shall be provided to each patient each year. It is felt that, commonly, patient need for medication outlasts the need for monthly psychotherapy. This is recognized in the federal initiative to move long stabilized patients into private physician office treatment.
5. **Standard:** 263.12 Psychosocial Staffing Patterns  
**Discussion:** The standard under Chapter 263 is currently written as a ratio of at least one counselor/therapist to 40 patients receiving treatment. It is noteworthy that this is a different ratio than applies to treatment facilities under Chapter 704. There is, therefore, no impediment to enacting P.A.M.P.'s recommendation to increase the ratio to one counselor for each 50 patients (in recognition of longer-term patients needing less counseling and the greater use of group therapy). It is also P.A.M.P.'s position that parts of 263.12 be struck which prohibit the counting of hours of counselors simply because they work less than 15 hours per week/1/3 full-time. Such restriction unfairly holds methadone programs to a different standard than other outpatient programs regulated solely by Chapter 704.
6. **Standard:** 263.13 Intake  
**Discussion:** P.A.M.P. members feel that the proposed language changes do not satisfactorily address readmission of persons formerly in treatment. It is our belief that, regardless of voluntary versus involuntary termination or number of years out of treatment, readmission be left entirely to the discretion of the program so long as current dependence is demonstrated.
7. **Standard:** 263.17 Termination  
**Discussion:** Because the Department has, correctly or incorrectly, interpreted this section to mean nonpayment is not in itself grounds for termination, P.A.M.P. believes that "nonpayment of fees" should be specifically included in the list of conditions. Whether provided on a "nonprofit" or "for profit" basis, many methadone programs would quickly go out of business were patients to perceive that they could stop paying indefinitely without being terminated from services.

The above represents issues about which there is broad agreement among P.A.M.P. members.

We strongly urge you to address these points prior to sending the proposed revision further along in the approval process. We have tried as an Association to focus only on those issues deemed most important although individual programs have numerous additional matters of concern. This document is intentionally succinct and we would be pleased to meet with you to discuss any or all of these issues.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Glen Cooper", written in a cursive style.

Glen Cooper, Vice President