Opioid Treatment Program Accreditation Impact Study— Executive Summary

1998-2002

Acknowledgements

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Part 1. OVERVIEW

On July 22, 1999, the U.S. Department of Health and Human Services (DHHS) proposed a new set of rules to transform the Nation's methadone treatment system from a regulatory system administered by the Food and Drug Administration to a mixed regulatory accreditation system under the oversight of the Substance Abuse and Mental Health Services Administration. An early step in this process was the study of the impact of such a transformation. This report presents key findings from the Opioid Treatment Program Accreditation Impact Study conducted on behalf of the Substance Abuse and Mental Health Services Administration (SAMHSA) from 1998-2002. The Study focused on a sample of opioid treatment programs (OTPs) undergoing accreditation on a voluntary basis. Appendices of this report include "lessons learned" from the participating accreditation bodies and from the technical assistance provided.

As had been anticipated, the decision to implement accreditation was made before this study ended. For that reason, the study was conducted as an impact, rather than a feasibility study. Ultimately, final results from this study supported the conclusion reached by the Secretary of DHHS to implement the regulatory change, as noted in the Final Rule (published January 17, 2001):

> "The Secretary believes that the interim results from the accreditation impact study confirm that the accreditation guidelines, along with the accreditation process itself, are a valid and reliable method for monitoring the quality of care provided by OTPs. The results indicate that most OTPs can achieve accreditation and that treatment capacity has not declined as a result. While SAMHSA intends to continue the study to fulfill its objectives, the Secretary does not believe that it is appropriate or necessary to delay implementation of these new rules until the full study is complete."

The final results of the OTP Accreditation Impact Study, presented in this executive summary, provide an important context in terms of considering the continuing development of the process of accreditation as overseen by SAMHSA.

Part 2. BACKGROUND

In the past few years, the opioid addiction treatment system has undergone vital changes, with implications for the quality, accountability, and effectiveness of pharmacotherapy (or, medication-assisted treatment) and related medical and psychosocial services being made available to people dependent on opiates. One of the most important has involved the adoption of accreditation, a long-accepted approach to ensuring treatment quality in other areas of health. Under a Final Rule, Title 42 of the Code of Federal Regulations, Part 8, published on January 17, 2001, and which took effect on May 18, 2001, opioid treatment programs (OTPs) were given until May 19, 2003 to achieve accreditation; in some cases this deadline was extended by one year. The preamble to the Final Rule described a process by which the Department of Health and Human Services (DHHS), in consultation with the Office of National Drug Control Policy (ONDCP), had concluded such a change was necessary to improve the existing regulatory system for the use of narcotic drugs in maintenance and detoxification treatment of opiate addiction.

The changes were proposed to replace the 30-year-old system of direct regulatory oversight of OTPs by the Food and Drug Administration (FDA) with a new, accreditation-based regulatory system. The new system would involve ongoing oversight by the Substance Abuse and Mental Health Services Administration (SAMHSA) and mandatory accreditation of OTPs by SAMHSA-approved accreditation bodies (ABs). Under this new system, the Secretary of DHHS may fully certify an OTP once it has been accredited by a SAMHSA-approved AB and complies with any other conditions for certification established by SAMHSA.

With this change, SAMHSA assumed the role once held by FDA as the DHHS agency delegated responsibility for carrying out statutory responsibilities required by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and modified substantially in the Narcotic Addict Treatment Act of 1974. Under these authorities, the Secretary of Health and Human Services is required to consult with organizations and the Attorney General to determine the appropriate methods for medically treating opioid (narcotic) addiction; to develop standards to determine whether practitioners are qualified to provide opioid treatment; and to determine that opioid treatment providers comply with standards that address the medical use of narcotic drugs provided to individuals for unsupervised use (also known as, "take home medication").

SAMHSA's new regulations represent a fundamental shift in the way our nation now approaches treatment for opioid dependence. They substantially and fundamentally reform the Federal government's role in assuring that OTPs provide quality treatment and are accountable for results.

WHY CHANGE WAS NEEDED

The change in regulatory oversight was precipitated by a series of critical reviews of the quality and effectiveness of opioid treatment by the General Accounting Office (the GAO, now called the Government Accountability Office) and by a 1995 study conducted by the Institute of Medicine (IOM) for DHHS. These reviews focused on the lack of systematic data on effectiveness, the variability in practice among OTPs, and concerns about the manner in which the Federal government was then carrying out its oversight responsibilities.

At the request of the Assistant Secretary for Health, an interagency working group, comprised of representatives from a number of Federal agencies, evaluated recommendations offered in the IOM report to determine if and how they could be implemented. This group focused on the IOM's recommendations to balance process regulations with clinical practice guidelines and quality assurance systems. The intention was two-fold: to allow OTP practitioners to exercise clinical judgment more freely in making treatment decisions, while continuing to provide accountability and enforceability of treatment standards.

After considerable deliberation, the Assistant Secretary for Health determined that a modified regulatory system that relied on private accreditation agencies that would periodically survey programs was feasible, and would be preferable to the existing FDA system, which relied solely on Federal regulations and Federally directed inspections. The interagency working group concluded that a professional accreditation system would also be more consistent with the oversight approach being used in most other health care fields. Also, it was felt that such an approach could better incorporate the use of consensually developed treatment guidelines to improve the quality of treatment provided. Finally, the group considered the accreditation approach to be more consistent with the requirements set forth by the authorizing legislation that called for DHHS to issue treatment standards and make recommendations to the Department of Justice (DOJ) concerning OTPs qualified to provide treatment.

SAMHSA's regulation (42 CFR, Part 8) sets forth, in detail, requirements for SAMHSA approval of both private, non-governmental organizations and State agencies as accreditation bodies and delineates the elements of OTP accreditation. In response to the IOM recommendations, the SAMHSA regulations spelling out the treatment standards were significantly reduced in scope to allow programs more flexibility and greater professional discretion in making decisions about treatment plans.

EXPECTATIONS FOR THE SHIFT FROM REGULATION TO ACCREDITATION

Generally, the shift to an accreditation approach was expected to strengthen the treatment system, improve the quality of treatment services at the provider level without compromising access to care as delivered by OTPs. Accreditation was believed to support increased professional discretion and medical judgment related to designing treatment plans based on individual patients' needs, in particular regarding medication management including "take-home" schedules, as well as determining on a case-by-case basis whether and when medically supervised withdrawals from medication might be undertaken. Development of accreditation standards specific to opioid treatment was expected to enhance oversight and also, accountability of OTPs. For instance, it was anticipated that application of these standards would promote state-of-the-art treatment services with an emphasis on outcome measures, especially those pertaining to reductions in crime and drug use, and engagement in productive employment.

The OTP Accreditation Impact Study was conceptualized and designed to examine the extent to which shifting from a regulatory approach to accreditation met these challenging expectations.

EVALUATING THE CHANGE

As part of a review and planning process to evaluate the impact of accreditation on the field of opioid treatment, SAMHSA created a "working laboratory," the OTP Accreditation Impact Study. This "working laboratory" was comprised of several components that proceeded concurrently with the rulemaking effort. These components included the development of clinical guidelines based upon the Center for Substance Abuse Treatment's (CSAT's) Treatment Improvement Protocols (TIPs) that address opiate addiction treatment, the development of opioid-specific accreditation standards, and an evaluation of the impact of new procedures on participating OTPs.

Two accreditation bodies, the Commission for the Accreditation of Rehabilitation Facilities (CARF) and the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), were awarded contracts from SAMHSA to use the CSAT clinical guidelines to develop "state of the art" accreditation standards for OTPs. These standards would incorporate both their current behavioral healthcare standards (e.g., administrative, clinical, infection control) and newly developed standards specifically addressing medication-assisted treatment (e.g., dosing, unsupervised use, diversion control, etc.).

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For the evaluation study, each accreditation body was contracted to conduct accreditation surveys on a sample of OTPs using their respective methodology and standards. SAMHSA also contracted with Johnson, Bassin, and Shaw (JBS) to provide training and technical assistance to the participating OTPs and logistical support for SAMHSA staff and the accreditation contractors.

Finally, SAMHSA contracted with the Research Triangle Institute (RTI) to carry out the evaluation of this working laboratory, "The Opioid Accreditation Program Accreditation Impact Study." Specifically, RTI was commissioned to assess the impact of accreditation through a systematic evaluation of the processes, barriers, and costs associated with the change to an accreditation system of opioid treatment. To meet these requirements, the Impact Study was designed as a pre- and post-test with a stratified random sample of programs to include sites undergoing accreditation (experimental) and sites not undergoing accreditation (control), to allow for comparisons.

The Impact Study was designed to identify changes that accreditation may prompt in clinical policies and practices and service accessibility and delivery within OTPs. Costs related to preparing for, undergoing, and achieving accreditation were also examined. The Impact Study was designed to measure the impact of accreditation at the OTP level, providing estimates of average OTP costs and labor hours across sites (looking at all sites) and also, considering these in light of site characteristics; the latter were defined by the key policy variables of ownership, size, and urbanicity. Also, given the critical role States play in the delivery of opioid treatment services, CSAT exercised an option within the Impact Study to complete a special study on State issues. This summary presents key findings from all study components.

As noted earlier, the Impact Study was not designed as a feasibility study to evaluate the effectiveness of adopting an accreditation-monitoring system. The idea of accreditation had already been determined acceptable. For that reason, this study was designed to examine the probable impact of accreditation on OTPs and the treatment system as a whole. Additionally, the study evaluated OTPs at two points in time relative to pursuing accreditation. However, it was not a longitudinal study with the capacity to capture the long-term impact of accreditation on treatment quality, or the costs of maintaining accreditation once achieved.

THE CSAT ACCREDITATION GUIDELINES

Concurrent to the commencement of the Impact Study, CSAT developed best practice guidelines in opioid treatment. In December 1996, CSAT convened a special field-based Guideline Development Panel of pharmacotherapy experts to provide content input as the Center began the process of developing guidelines for accreditation organizations. An Expert Review Panel was held on January 14, 1998, to review and further refine the draft document. The document was also circulated for review and comment to additional treatment experts and Federal officials (Center for Substance Abuse Treatment, 1999).

The CSAT Accreditation Guidelines outlined the results to be expected of a monitoring system based on accreditation:

- Improved quality of care and reduced variability in the standard of care provided to patients.

- Increased professional discretion in providing medical care and developing individualized treatment plans.

- Positioning of opioid treatment more closely within mainstream health care, thereby potentially expanding the availability of treatment within hospitals and health maintenance organizations, both of which are accustomed to meeting accreditation standards.

- Helping reduce the stigma often associated with opioid treatment.

- Increasing the focus on performance outcomes.

The following domains, as recommended by the Guideline Development Panel, organize the guidelines. These domains are representative of those delineated in the *Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Final Rule* and serve to drive the development and revision of accreditation standards.

- Administrative Organization and Responsibilities
- Management of Facility and Clinical Environment
- Risk Management and Continuous Quality Improvement
- Professional Staff Credentials and Development
- Patient Admission Criteria
- Patient Medical and Psychosocial Assessment
- Guidelines for Therapeutic Dosage
- Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment
- Testing for Drug Use
- Unsupervised Approved Use ("Take-home Medication")
- Withdrawal and Discharge
- Management of Concurrent Alcohol and Polysubstance Abuse
- Concurrent Services
- Special Considerations
- Care of Women in Treatment
- Patients' Rights
- Record Keeping and Documentation
- Community Relations and Education
- Diversion Control

The domains and guidelines also served to drive the analytic plan for the Impact Study providing an outline of critical components of opioid treatment for the evaluation. In turn, a primary objective of the Study was to inform the guidelines as to the impact of accreditation on the field of opioid treatment.

Accreditation standards implemented during the Study were based directly on these CSAT accreditation guidelines.

GENERAL AIMS OF ACCREDITATION

- Private accreditation is a form of quality oversight. Under an accreditation-based system, organizations plan, organize, and run their programs in concert with a published set of standards. Programs then apply for a review against these standards, and if they sufficiently conform to the standards, they are awarded an accreditation certificate. To ensure that services and supports are being effectively monitored and evaluated and held to high performance expectations, national accreditation bodies share many common principles and approaches. These principles have evolved over the years and reflect the purposes, values, and vision of the accreditation organization. The typical national accreditation body embraces the following principles:

- The development and maintenance of state-of-the-art standards that provider organizations can use to assess and improve the quality of their programs. These standards are often performance-

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based and consumer-focused and address key processes providers must use to produce positive outcomes.

- The inclusion of various stakeholders, including consumers, providers, and purchasers, in the governance of the accreditation body and the development of standards.

- The provision of independent, impartial, experienced, and qualified peer reviewers as surveyors.

- The application of standards in periodic on-site visits where services are actually delivered.

- The provision of suggestions and consultations during the site survey, along with the application of standards and evaluation of the organization's policies, processes, and performance.

- The provision of a survey report following the site visit with observations, commendations, suggestions, and recommendations to improve conformance to standards where the organization has demonstrated deficiencies.

- The requirement that the provider organization prepare and submit a quality improvement plan to address program deficiencies as identified in the survey report.

**Part 3. EXECUTIVE SUMMARY AND RECOMMENDATIONS
            from The Opioid Treatment Program (OTP) Accreditation Impact Study,
            1998-2002**

INTRODUCTION

In 1995, policy makers contemplated and began planning the shift in oversight of opioid treatment programs from the Food and Drug Administration (FDA) to the Substance Abuse and Mental Health Services Administration (SAMHSA). In 1998, data collection commenced for a SAMHSA-commissioned study entitled, "The Opioid Treatment Program (OTP) Accreditation Impact Study" ("Impact Study"). At that point, it was anticipated that the decision to implement accreditation would be made before the study concluded, and for that reason, it was conceived as an impact rather than a feasibility study.

The key findings that follow include highlights from the major components of the Impact Study. Baseline findings provide a valuable description of OTPs at a time prior to accreditation. We also draw attention to the implications suggested by the 'change' findings, which describe the potential impact of accreditation on the field of opioid treatment and for that reason, may prove useful to SAMHSA as the agency continues to implement and refine the new regulatory scheme. Finally, given the critical role States play in the delivery of opioid treatment services, this report concludes with highlights from a special study on State issues conducted as part of the overall evaluation.

The final results, summarized here, provide important context in considering the continuing development of the process of accreditation as overseen by SAMHSA, of the field of substance abuse treatment in general and of opioid treatment in particular.

Generally, it is hoped that the findings and implications contained in this report will be used by SAMHSA and also State agencies and accreditation bodies, OTPs and the professionals who work in this field, and patient advocates, for purposes ranging from refining the CSAT accreditation guidelines to better targeting education and technical assistance opportunities to OTPs.

To pursue the study of accreditation and its impact on OTPs and the field of opioid treatment, now that accreditation has become mandatory, SAMHSA commenced a new, three-year study in the fall of 2002. That study explores the issues related to maintaining accreditation as well as achieving it for the first time.

PURPOSE AND METHODOLOGY OF THE "IMPACT STUDY, 1998-2002"

<u>A representative sample</u>

The Impact Study focused on a sample of 172 programs in 15 states that underwent accreditation on a voluntary basis, generally for the first time, and during a period when the field of opioid treatment was well aware that a change in regulatory oversight was underway. The movement to a national accreditation system was under consideration. For that reason, it was critical that data from the study could be generalized to the nation as a whole.

Sampling took place in two stages—first, with the selection of States, and then, the selection of sites within the States. In view of limited resources, States were selected purposively, both for the practical purpose of controlling travel and site visit costs, but also, and more importantly to ensure broad representation of key policy considerations. The States included California, Colorado, Connecticut,

Florida, Georgia, Illinois, Indiana, Maryland, Massachusetts, Michigan, Missouri, Nevada, New York, North Carolina and Texas.

In addition, the evaluation team determined statistical weights to ensure that the sample of OTPs in the study adequately represented the universe of OTPs across the country in terms of critical policy variables (such as size of the OTP). In reading this report, it should be noted that data presented throughout are based on these adjusted weights.

Purpose and design considerations

SAMHSA charged the evaluation team with assessing the impact of accreditation through a systematic evaluation of the processes, barriers, and costs associated with the change to an accreditation system of opioid treatment. To this end, the study was designed as a pre- and post-test (pre- and post-accreditation) with a stratified random sample of programs to include sites undergoing accreditation (experimental) and sites that would delay accreditation until after study data were collected (control). This would allow for comparisons before and after undergoing accreditation, and also, between programs that underwent accreditation during the evaluation study and those that underwent delayed accreditation versus natural changes in the field of opioid treatment. It should be noted that, although the study evaluated OTPs at two points in time, it was not a longitudinal study with the capacity to capture the long-term impact of accreditation on treatment quality, or the costs of maintaining accreditation once achieved. In retrospect, a limitation of the study was the necessarily narrow 6-month follow-up period; on-site observation by the evaluation team suggested that in many cases OTPs were 'on the way' to implementing change, but change that would not become visible until some point in the future.

The results here are presented in terms of baseline findings–the information gathered initially, in this case, 6 months before programs underwent accreditation (for those that did)–and 'change' findings. 'Change' alludes to changes accreditation prompted, for instance, in clinical policies and practices and service accessibility and delivery within OTPs. The Impact study also examined costs related to preparing for, undergoing, and achieving accreditation. Importantly, impact was assessed at the OTP level, allowing for the derivation of estimates of average OTP costs and labor hours across sites (looking at all sites). Cost and resources were also considered in light of site characteristics, for instance as defined by three key policy variables that guided the analysis: ownership, size, and urbanicity. These key policy variables are defined below.

Data Collection Timelines

The following activities were included in this study:

> • *For OTPs that underwent accreditation as part of this study (experimental sites),* the design called for data to be collected at baseline and follow-up, in this case 6 months prior to, and 6 months following each OTP's accreditation survey (conducted by the accreditation body).
>
> The time frame for these site visits assumed that at 6 months before its accreditation review, an OTP would operate in a near-steady state; that activities in the OTP would change dramatically as final preparation for the accreditation survey was under way (in the few months immediately preceding the accreditation survey); and that 6 months following the accreditation survey, the OTP would have returned to a steady state (at which point follow-up Impact Study visits were planned).[1]

[1] Delays in implementation arising from concerns expressed by the Office of National Drug Control Policy led to changes in the original evaluation design and protocol. For a number of sites, the period between the baseline

• *For sites undergoing delayed accreditation (control sites) as part of the study*, data were collected mirroring the schedule for experimental sites in order to monitor trends in the field of treatment for opioid dependence.

Comparisons between experimental and control sites (sites undergoing accreditation within the evaluation study timeline and sites undergoing delayed accreditation) are based on data gathered in the same time interval.

FRAMING THE ANALYSIS: KEY POLICY ISSUES

Organizational characteristics such as ownership and size continue to be highlighted in studies of drug abuse treatment as impacting patient characteristics, services, and access to services. Programs' experience with accreditation, and determination of its impact in the for-profit sector as distinct from the non-profit/public sector, and in small versus large treatment programs are thus areas of important policy concern. An additional long-term policy concern in the pharmacologic treatment of opioid dependence is access to care, related to which a CSAT publication, "Changing the Conversation, Improving Substance Abuse Treatment: The National Treatment Plan Initiative," highlighted issues of access to treatment in rural and underserved areas.

As these three organizational characteristics−ownership, size, and urbanicity−are at the center of policy discussions regarding the impact of accreditation on opioid treatment, the Impact Study defined these variables as key policy variables and incorporated these into the analyses. For instance, these policy variables are addressed in the baseline and change analyses highlighted in this summary, toward evaluating the impact of each on critical components of opioid treatment at a time prior to accreditation. These same policy variables have been used as independent variables in regression analyses aimed at evaluating the impact of accreditation on critical OTP characteristics at a time after accreditation.

For purposes of these analyses, the policy variables were defined as follows:

- *ownership status*: for-profit or nonprofit/public;

- *program size*, basing this on the program's current average daily census of patients as reported by the site director in the site director's questionnaire: small, equal to 1 to 100 patients; medium, equal to 101 to 300 patients; and large, equal to more than 300 patients;

- *urbanicity*, using Beale urbanicity codes, which for the study were derived using the sites' ZIP codes: nonurban, being equal to a site located in an area with less than 250,000 population; urban, equal to a site located in an area with 250,000 to 1 million population; and large urban, equal to a site located in an area with more than 1 million population.

(initial) site visit and the accreditation survey exceeded 6 months, in several cases, over 12 months; adjustments were made in the analysis.

Thus, through the Impact Study[2], we have:

(1) described characteristics of OTPs

(2) determined costs and activities associated with pursuing accreditation, and

(3) identified correlates associated with a successful accreditation outcome from an OTP's first accreditation survey.

KEY FINDINGS–BASELINE ANALYSES

From September 1998 to February 2000, approximately six months prior to the programs' respective accreditation surveys, the evaluation team initiated baseline site visits to 172 OTPs in 15 States. Ultimately the evaluation team completed visits to 152 OTPs, following some drop-outs prior to initiating the protocol, shifts between accreditation bodies, and similar events. These included both experimental and control programs, in other words, programs that underwent accreditation as part of the study and programs that delayed accreditation, as indicated in the following tables:

	Accreditation Body		
	CARF	*JCAHO*	*Combined*
Experimental	80	48	128
Control	28	16	44
Total	108	64	172

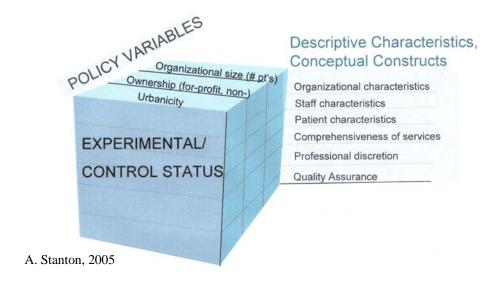| Original Number of OTPs	172
Dropouts	- 20
Final Total	152

Univariate analyses of the key policy variables (size, ownership and urbanicity) were conducted. These showed that OTPs participating in this study ranged in size from 20 patients to just under 2,000. At the time of this study, just over half (54%) were non-profit or public OTPs; the remaining 46% were for-profit organizations. The majority was located in urban or large urban areas, and 58% were members of larger parent organizations. Study findings also suggest that much of the growth in the opioid treatment system has been in the for-profit sector. On average, for-profit sites were founded more recently than non-profit OTPs, with over 60% of for-profit OTPs having been in operation 10 years or less, compared with 30% of the non-profit OTPs. Overall, there were minimal differences between programs related to the key policy variables of ownership, size, and urbanicity.

The findings that follow are organized in terms of the three constructs describing organizational, staff, and patient characteristics; and the three conceptual constructs of comprehensiveness of services, professional discretion, and quality assurance.

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[2] Corresponding analytic tasks included summarizing the main measures collected in the surveys, identifying the most important variables and constructs to be used as outcomes, showing the relationships between these selected outcomes and the Impact Study key policy variables of interest (ownership, size, and urbanicity), testing the effect of going through the accreditation process on changes in outcomes and identifying correlates associated with successfully achieving accreditation. Data were analyzed in such a way as to answer the study's central questions about the processes and impact of accreditation.

A. Stanton, 2005

Baseline analyses from the study provided a comprehensive descriptive 'snapshot' of the field of treatment prior to accreditation. These results also informed subsequent 'change' analyses evaluating the impact of accreditation on opioid treatment services

Organizational Characteristics

Staff Training

- OTP policies and approaches to staff training varied markedly. At some sites, staff reported attending no training in the 6 months prior to baseline data collection, while at others, all staff reported having attended training. No associations were found between the proportions of staff attending training and OTPs' encouraging or requiring training, suggesting that other factors are shaping staff training activities. No differences were found related to ownership, size, or urbanicity.

Emergency Access

- OTP policies were examined for indications that programs are ensuring patients have after-hours access to care. At baseline, a little less than a quarter of OTPs, both experimental and control, had some system in place, with a 24-hour crisis service number (used in 56% of these OTPs) being the most often employed. This finding did not vary with program size, ownership, or location.

Community Input

- Community representation on a governing board was found more often with non-profit OTPs than for-profit OTPs (nearly 90%, as compared with 26%).

Treatment Orientation (Philosophy, Practice, and Dosing)

- Treatment orientation, as defined by treatment philosophy, practice, and dosing, does not appear to vary according to ownership or urbanicity. Also, no association was found between program size and either treatment practice or patient involvement in dosing. However, evaluators did find a statistically significant association between OTP size and treatment philosophy. Namely, the largest sites were more likely to offer maintenance-oriented treatment, this in turn usually involving higher methadone doses and no time limit on treatment.

Cost of Treatment, Pre-Accreditation:

- On average, the estimated annual cost per patient for opioid treatment in year 2000 dollars was $4,176.

- For non-profit/public sites, the estimated cost per patient was $4,580, compared to $3,713 for for-profit sites.

- The average per-patient cost at small sites was $5,216, for medium sites $3,996, and for large sites $3,812, suggesting some cost efficiencies related to the size of the patient base.

- On average, for-profit sites received a higher proportion of per-patient funding from patient fees. Sites that were part of a larger organization also reported higher per-patient funding.

Staff Characteristics

Staff Demographics

- Looking at all OTPs, more than half of staff members were white and non-Hispanic. Only 17% of staff were in recovery. More than two-thirds of all direct care staff (staff with active caseloads) were women. Almost half of counselors were 45 years of age or older, with significantly older counselors being employed by non-profit sites.

Staff Experience

- Direct care staff tended to be experienced in the field of substance abuse treatment and had gained some of this expertise in non-methadone-specific drug treatment programs. Nearly half of all counselors, nurses, and case managers, and an even larger percentage of clinical supervisors reported 6 years or more of substance abuse treatment experience.

Staff Certification

- Generally, the percentage of direct care staff with some form of substance abuse treatment certification (CDAC, CADAC, CAC, and state certification) was relatively low–less than half of case managers and counselors and only two-thirds of clinical supervisors. More staff members were certified in small and non-profit sites compared to larger and for-profit sites.

- The most common certification required for counselors was state certification. 35% of all sites required state certification and 25% required national certification.

Staff Training

- Staff training was inconsistent across OTPs. Overall, direct care staff members with a caseload indicated they had attended four training events in the past 6 months and 30 hours of training in the past year. At larger sites, however, direct care staff had attended a significantly greater number of training events in the previous 6 months.

Staff Interaction with Patients

- Of the total hours worked by direct care staff with caseloads, approximately half were spent interacting with patients. Only 22% of their time was spent doing paperwork.

Staff Perceptions

- Virtually all staff found working relationships to be "somewhat supportive."

- Most staff considered their workplace to be "better than most."

- Direct care staff members were more likely to describe medical and psychological services as adequate than other services such as housing/food or legal services.

- Somewhat less than half of staff (44%) perceived automated methadone dispensing as acceptable.

Physician Demographics

- Physicians in OTPs were primarily white and male, with over 10 years of substance abuse treatment experience. Only 22% of physicians were women.

Physicians' Time

- Physicians were typically employed only part-time an average of 16 hours per week of work on site.

- Approximately half of their time on site was spent conducting initial physical examinations and reviewing patient dosing levels. Physicians reported spending 26% of their time completing administrative tasks.

- At larger sites, physicians spent a significantly smaller percent of their time reviewing patient dosing than other clinical and administrative activities. This was also true of physicians in large urban areas.

Physician Perceptions

- Generally, physicians were more likely to describe medical and psychological services as fully adequate compared to other types of services. Even so, only half of physicians described medical and psychological services as fully adequate.

- More than two-thirds of physicians considered their program sites to be better than most. Physicians at for-profit sites were significantly more likely than physicians at non-profit sites to describe their sites as better than most.

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<u>Patient Characteristics</u>

Patient Demographics

- Consistent with other large-scale studies on methadone treatment, the Impact Study found populations of methadone patients to be demographically and socially diverse, but also, aging as compared to earlier studies of methadone treatment patients. The population was primarily over 35 years of age (78%).

- The patient population was 57% male and 43% female. Almost three-quarters were non-Hispanic (75%) and about half, white (56%).

- Half (50%) of patients reported being employed 35 hours or more per week.

- Significant associations were found between patient race and organizational characteristics. For the most part, white patients reported being treated in for-profit, small, and either urban or nonurban OTPs. Conversely, African American patients reported being treated in non-profit, large, and large urban OTPs.

Physical and Emotional Health

- In assessing their current health, females were less likely than males to evaluate their health as excellent or very good. Regarding psychological health, women were significantly more likely to report having difficulty performing regular activities due to emotional health issues.

Health Insurance

- Female patients were significantly less likely to report having health insurance.

- Patients at small sites were more likely to report having no insurance than those at larger sites. Similarly, more patients at non-urban sites reported lacking insurance than patients at sites located in more urban settings.

Alcohol and Substance Use

- Patients' continued use of alcohol and other drugs decreased following a minimum of 6 months of treatment.

- Patients at non-profit sites reported less marijuana use and more cocaine use compared to patients in for-profit sites. Heroin use was significantly associated with site size, with patients at smaller sites tending to report more heroin use compared to patients at larger sites.

Patient Involvement

- Patients at for-profit sites reported significantly higher rates of involvement in decisions about their treatment than those at non-profit sites.

- Similarly, patients at small sites reported significantly higher rates of involvement in decisions about their treatment than those at medium or larger sites.

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Patient Satisfaction

- A large majority of patients (80%) reported that they had been treated fairly by their site staff in the 3 months previous.

- More than half (58%) of patients rated their treatment as very good or excellent.

Comprehensiveness of Services

Patient Placement

- At the time of baseline data collection conducted for this study, more than half of the sites required staff to use specific criteria for placement. Of those sites, most (76%) used DSM-IV criteria, and 66% used criteria developed by the site or program to evaluate patients. A great deal of variation among sites was found in the mix of different criteria used to place patients.

- Significant differences in placement criteria were found in terms of site ownership. Of note, non-profit sites were more likely than for-profit sites to require staff to use placement criteria for all patients (71% compared with 39%).

Patient Assessment

- Non-profit/public OTPs are more likely to require specific criteria for patient assessment than for-profits (72% versus 39%).

- In terms of instruments used, 11% of sites used the Addiction Severity Index (ASI) only, 12% used a combination of ASI and program-developed criteria, and 6% used ASI or program-developed and other assessment instruments. Over 41% used only a questionnaire for patient assessment. Significant differences were seen by urbanicity–staff members at urban sites were more likely to report not using any assessment instrument, and if one was used, were more likely to use solely an instrument developed by the site.

- Costs per session for initial patient assessment were significantly greater for non-profit/public sites compared to for-profit sites. This result is explained in part by the greater average time spent per patient at non-profit/public sites, with non-profit/public reporting an average of 127 minutes per initial patient assessment compared to 94 minutes reported by for-profit sites.

Core Services

Individual and Group Counseling

- Individual counseling was by far the service patients most often reported receiving. Specifically, more than three-fourths (77%) of patients reported receiving individual counseling, while only 43% reporting receiving group counseling.

- Patient reports were in tandem with reports from the sites. Most sites (88%) reported that the majority of their patients received individual counseling services. For-profit sites reported offering significantly more individual counseling sessions per month than non-profit sites, however (2.6 compared to 2.2).

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- Also meshing with patient reports, sites reported that group counseling was offered less than individual counseling. Almost half (46%) of sites reported providing group counseling to 10% or less of their patients. Non-profit sites reported offering significantly more group counseling sessions (3.9) than for-profit sites (1.6). This finding was also true of large sites, which reported a mean average of 4.3 group counseling sessions offered per month, compared with 2.2 sessions at medium sites and 2.1 at small sites.

- Costs for individual counseling were significantly different depending on site size and urbanicity. Related to this, small sites spent significantly more time per patient (47 minutes) on individual counseling than did medium (46 minutes) or large sites (37 minutes). Sites in nonurban areas reported significantly higher total costs for individual counseling sessions ($42) compared to urban ($30) and large urban ($37) sites. This was true of group counseling costs as well, with sites in nonurban areas again reporting a higher per-patient group counseling cost ($11) compared to sites in urban ($7) and large urban sites ($9).

Medical and Psychological Services

- About a third of patients (31%) reported receiving general medical care.

- Virtually all sites reported offering medical and psychological services; however, only one-third provided on-site general medical services, and one-fifth provided on-site HIV/AIDS medical services.

- Non-profit sites were significantly more likely than for-profit sites to offer a greater number of general medical care services, HIV/AIDS-related medical care services, psychological services, and/or post treatment follow-up/aftercare services, either onsite or at another program (2.4 services versus 1.5). The same was true of large sites, which offered 2.5 services compared to 1.8 at medium sites and 1.6 at small sites.

- Alternately, for-profit sites reported a greater number of medical and psychological services offered through referral only (2.2 compared with 1.6 at non-profit sites).

Services for Drugs of Abuse Other than Heroin

- Nearly 23% of patients reported receiving treatment for use of other substances besides opiates.

- Virtually all sites indicated they provided services for drugs other than heroin; these included detoxification from a substance other than heroin and ongoing treatment for addiction to alcohol, cocaine, or other illicit drugs.

- Non-profit/public sites offered a significantly greater number of these services on site or through a combination of on site and other program sites (2.6 services versus 1.7 of services offered by for-profit sites).

Ancillary Services

- As might be expected, ancillary services including educational, vocational, financial, legal, family, housing/shelter, and acupuncture services, were much less likely to be available compared to the core services of counseling, medical care, and psychological services.

- Non-profit sites were significantly more likely than for-profits to offer a greater number of ancillary services onsite or at another program (1.8 services versus 0.7 services offered by for-profit sites).

- Non-profit/public sites were also significantly more likely to offer transportation and child-care services, and more likely to provide these services on-site than were for-profit sties. Even so, transportation services were offered directly only by about half (53%) of non-profit/public sites, and only 17% of non-profit/public sites offered childcare directly.

Professional Discretion

Physician Activities

- About 80% of physicians reported that they routinely reviewed treatment plans. About 70% reported that they routinely attended clinical staff meetings.

Time in Treatment

- The majority of physicians (66%) reported that medical decision determined the maximum time patients spent in treatment.

Dosing

- The average methadone dose upon admission was 34 mg./day.

- The average daily maintenance dose of methadone was 69 mg. Maintenance doses ranged equally among the categories of 40-59 mg./day, 60-79 mg./day, and 80-99mg./day.

- Approximately 15% of patients received doses of less than 40mg./day, while about 13% received doses of 100mg./day or more.

- Methadone dosing costs were approximately $24 per patient per week. Small sites had greater methadone dosing costs /patient/week.

- Sites spent an average 22 minutes/patient/week on methadone dosing.

Maximum Dose

- The majority of physicians (90%) reported using medical decision and Federal regulations, to determine the maximum dose a patient may receive.

- Urban sites reported the highest proportion of patients receiving methadone doses of 100 mg./day or more (15%), while large-urban sites reported that 12% of patients received 100 mg./day or more. At non-urban sites, fewer patients (7%) received 100mg./day or more.

- About 61% of physicians reported a particular maximum dose that they would almost never exceed. The average "maximum not-to-exceed" dose was 148 mg./day, although responses concerning these doses ranged between 40 mg./day and 600 mg./day.

Unsupervised Medication Use

- The majority (69%) of patients in treatment less than one year did not receive take home medication. However, the proportion of patients with 3 or more take-homes per week (15%) was higher than the proportion with one or two take home privileges per week. The distribution of take-home privileges did not differ by OTP ownership, size, or urbanicity.

- Among patients who had been in treatment a year or longer, 41% had 3 or more take-home doses per week. The percentage ranged from a low of 36% at large OTPs to a high of 46% at urban OTPs. However, these differences were not statistically significant.

 Medical Withdrawal

- About 66% of physicians reported that medical evaluation sometimes leads to decisions to initiate medical withdrawal. However, the most frequently reported reason (75%) given for medical withdrawal was "patient's decision – against medical advice."

- The mean average length of time reported by physicians for medical withdrawal was 16 weeks; however, there were significant differences depending on urbanicity. While urban sites reported 13 weeks, and large urban reported more than 17 weeks, non-urban sites reported an average of only 8 weeks.

Treatment Planning/Monitoring and Evaluation

- Physicians responded that they determined maintenance dose on an individual basis. There were no differences concerning maintenance dose practices among programs in terms of the key policy variables.

- Overall, findings indicate that professional discretion played a major role in treatment monitoring, under the FDA regulatory system in place at the time of this study. Physicians appeared to be involved in the ongoing treatment of patients. Medical decision was the primary determinant of maximum time in treatment and dosing level. While detoxification was encouraged to some extent, physicians' medical evaluations remained a major factor in determining whether withdrawal should be initiated.

Performance Measurement/Quality Assurance

Quality Assurance (QA)/Continuous Quality Improvement (QCI) Processes

- A large percentage of OTPs reported having QA/CQI processes and procedures; however, the content and form of these procedures varied by OTP ownership, size, and urbanicity. Generally, non-profit/public sites were more likely to monitor treatment outcomes and trends. Larger sites in large urban areas tended to have more formalized QA procedures in place, while smaller sites in non-urban settings relied more heavily on a review of patient charts.

- Non-profit/public OTPs were more likely than for-profit OTPs to have both ongoing QA/CQI and written QA/CQI procedures.

- Only 69% of OTPs reported collecting data on outcome indicators and monitoring trends.
  - OTPs located in non-urban areas were significantly less likely than those in large urban areas or urban areas to do so. Non-urban OTPs were also less likely to assess patient satisfaction with services.
  - Non-profit/public OTPs were significantly more likely than for-profits to collect data on indicators of outcomes and to monitor trends. These same sites were also significantly more likely than for-profit sites to assess patient satisfaction.

Quality Assurance/Continuous Quality Improvement Activities

- Similar to small OTPs, non-urban OTPs were more likely than other OTPs to review records of patients with special conditions.

- About half of OTPs reported having all clinical staff or lead counselors regularly attend QA meetings.

- More than twice as many for-profit/public sites (71%) reported that all clinical staff attended QA meetings than did non-profit/public sites (32%).

- As noted above, non-urban OTPs were less likely to assess patient satisfaction with services than other sites; and non-profit/public OTPs were significantly more likely (93%) than for-profit (83%) sites to assess patient satisfaction.

- Of the 172 OTPs included in the study, 41 reported already being accredited by CARF or JCAHO.

- On average, sites reported spending approximately 8 minutes per patient per week on quality assurance activities. For those sites that reported the hours spent on QA, the estimated weekly cost per patient was close to $8.00. Significant differences were found in the mean average costs of QA between for-profit and non-profit/public sites, with higher weekly patient costs at the non-profit/public sites ($9 versus $6).

KEY FINDINGS–THE CHANGE ANALYSES

Six months (or in some cases, longer) after programs underwent their accreditation surveys, the evaluation team returned to collect follow-up data needed to conduct subsequent "change" analyses. Participants are detailed in the table below. Basically, of the 144 OTPs that completed follow-up site visits as part of the evaluation study, 104 underwent the accreditation process as experimental sites, and 40 were control sites.

SITE CLASSIFICATION	NUMBER OF SITES
Experimental	
Completed baseline survey	128
Dropped out of study	18
Passed over (not ready for accreditation site visit within study timeframe)	8
Outlier, dropped from analysis	1
TOTAL EXPERIMENTAL SITES AVAILABLE FOR FOLLOW-UP	**104**
Control	
Completed baseline survey	44
Dropped out of study	2
Outlier, dropped from analysis	1
Group classification error	1
TOTAL CONTROL SITES AVAILABLE FOR FOLLOW-UP	**40**
TOTAL FOLLOW-UP SITES………………….	**144**

For the Impact Study, "change" was examined in terms of changes seen between the time prior to accreditation (with data collected at baseline) and after OTPs underwent initial accreditation (follow-up data, collected approximately six months afterward). In addition, comparisons between programs that underwent accreditation and those that did not helped ensure that differences were more likely associated with undergoing accreditation than some other factor affecting all programs.

In the following discussion, key findings from the Impact Study are presented and discussed related to each of the three general areas examined in the 'change analysis.' In some cases, recommendations are offered as suggested by the findings. The findings are organized in the following manner:

1. Process and Outcomes of Accreditation:

    - accreditation outcomes
    - program characteristics associated with achieving accreditation
    - staff perceptions of accreditation, and
    - costs of accreditation[3].

2. Impact of Accreditation on Treatment Services:

    - changes in organizational, staff, and patient characteristics,
    - changes in comprehensive services,
    - changes in professional discretion, and
    - changes in performance measurement.

3. Role of States under an Accreditation System:

    ▪ Issues and areas of concern identified by key stakeholders

The Process and Outcomes of Accreditation

Accreditation Outcomes

For the Impact Study, accreditation outcomes were analyzed using two separate approaches:

(1) the outcome of the OTP's initial accreditation survey, with possible outcomes reduced to a binary (yes/no) variable describing whether an OTP was or was not able to achieve accreditation in its first survey, and
(2) the number of recommendations (deficiencies or citations) identified by the accreditation body's survey team at the initial visit.

These two variables were then also considered in terms of their relationship with organizational and staff characteristics, staff perceptions of the accreditation process, and the cost of pursuing accreditation.

Did the Program Achieve Accreditation on the First Try: Yes/No[4]:

Finding:

• Of OTPs in the experimental sample–those that underwent accreditation during the course of the study–86% achieved accreditation during their initial accreditation survey.

Discussion: Historically, accreditation has not been as widely employed by substance abuse treatment programs as it has been by other health care facilities and programs. For this reason, the shift to an accreditation regulatory system represented a critical change in treatment practice for the field of opioid treatment. Comments received from stakeholders, professional organizations, health professionals and others in the field of opioid treatment in response to the proposed regulations affirmed support for accreditation as an effective system, but expressed the trepidation felt by many concerning the readiness of opioid treatment providers to achieve accreditation.

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[4] The two accreditation organizations participating in the Impact Study differed in their definitions of accreditation outcomes. CARF accreditation outcomes included nonaccredited, 3-month abeyance, 1-year accreditation, and 3-year accreditation. The category of 3-month abeyance was a special accreditation outcome created solely for the Impact Study; it indicates that a survey visit occurred and no final accreditation decision was rendered. OTPs with 3-month abeyances were expected to schedule a re-survey within 3 months, at which time they would obtain a final accreditation outcome (1 year, 3 year, or nonaccreditation). JCAHO accreditation outcomes in this study included nonaccreditation, conditional accreditation, and accreditation with Type 1 recommendations.

For the purposes of initial predictive analyses of accreditation outcomes, analysts created a binary indicator of whether the OTP achieved accreditation within the time frame of the study. OTPs were considered to have achieved accreditation if they received a 1-year or 3-year accreditation from CARF, or accreditation with Type 1 recommendations or conditional accreditation from JCAHO. OTPs were considered not to have achieved accreditation if they received a nonaccreditation from either accreditation body, if they received a 3-month abeyance from CARF, or if they were not ready or able to submit the application to schedule an accreditation survey within the time frame of the study.

Actual findings of the Impact Study suggested that the majority of OTPs would be successful in achieving accreditation as the system is currently designed–that accreditation would not pose the hurdle initially anticipated by the field and by key stakeholders.

How *many* recommendations (deficiencies, citations) did programs receive, and in which areas?

To enable a more in-depth analysis of characteristics associated with achieving accreditation, the evaluation study staff needed to devise a way to characterize accreditation outcomes in a way that more fully reflected the complexity of the real-world process.

To this end, staff defined outcomes in terms of specific accreditation standard "recommendations" received by OTPs during accreditation surveys. In accreditation terms, a "recommendation" means that an accreditation body has indicated a standard citation (specific area of noncompliance with accreditation standards) that needs to be addressed by an OTP.[5] Using this information to 'fill in the picture' about accreditation outcomes would give a better sense of how well programs did, including areas of strength or where there was room for improvement.

Analyses were conducted at the site (OTP) level. To enable the most powerful comparisons of sites that underwent accreditation as part of the study with sites that did not, the analysis used aggregate data from 68 OTPs in the CARF sample.

Findings:

• The average number of standard citations was 68. The actual number of citations ranged from 1 to 206.

• Overall, OTPs received the most standard citations in the domains of organizational administration, screening and assessment, and performance improvement.

• Overall, OTPs received minimal standard citations in the methadone treatment practice areas of medication use, dosing, take-home dosing, and drug screening.

Program Characteristics Associated with Achieving Accreditation

Findings:

• Size and urbanicity did not predict *whether* or not programs achieved accreditation.

• However, on average, small and nonurban OTPs received more standard citations during their accreditation surveys than did large and urban OTPs.

• For-profit OTPs received significantly fewer total standard citations during the accreditation site visit than did non-profit OTPs.

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[5] For purposes of analysis, the Impact Study staff collapsed the CARF and JCAHO standards that appeared in the 1998 CARF and JCAHO Behavioral Healthcare Standards manuals used during the study into 16 accreditation recommendation domains, thus combining the individual CARF and JCAHO standards. Further, these domains were organized into two categories: (1) standards that addressed general behavioral healthcare, and (2) standards specific to methadone treatment.

• OTPs that offered a higher level of comprehensive services (defined primarily as core and ancillary services offered by the OTP, HIV/AIDS-related care, and the number of special services offered on-site at the OTP) before accreditation received significantly fewer total citations during the accreditation survey.

Discussion: As OTPs move toward pursuing accreditation, a critical question becomes not only, how many are achieving accreditation, but "What characteristics of OTPs are related to accreditation survey outcomes?" Limited variation among the programs in terms of outcomes in turn limited the analysis of characteristics associated with achieving accreditation. Nonetheless, findings from the Impact Study will help identify or verify program types for which accreditation may prove more of a burden, for instance small and rural OTPs, as was anticipated in the proposed rule. Additionally, these findings should guide OTPs in targeting their preparation for accreditation surveys, and the Federal government in targeting valuable technical assistance dollars more efficiently and effectively.

Considered in terms of the key policy variables, these findings suggest that organizational size or location did not directly influence these OTPs' ability to achieve accreditation (or not). However, small and nonurban sites received more standard citations during their accreditation reviews than did other types of programs. Ownership status, on the other hand, also appeared to be related to the number of standard citations received. Potentially, other organizational characteristics, such as organizational quality and health and safety procedures, may be at work, rather than a direct link to ownership status. Another predictor of success in achieving accreditation included comprehensiveness of services offered through OTPs.

Recommendations:

• The OTP trainings conducted by accreditation bodies should emphasize the standard domains of organizational administration, screening and assessment, and performance improvement.

• Accreditation body standards, CSAT accreditation guidelines, and SAMHSA TIPs should continue to promote the need for staff development through both internal and external training, and encourage support for staff to become credentialed as a means for improving quality of care. Under the accreditation approach, a key element in providing effective treatment is implementing an active quality assurance program, which should include credentialing of key clinical personnel.

• Accreditation standards, CSAT accreditation guidelines, and professional publications should continue to stress the need for OTPs to utilize standardized procedures and tools to assess patients' needs for core and ancillary services, and to have these services available to meet those needs, if OTPs are to provide the most comprehensive opioid treatment**.**

<u>Staff Perceptions of Accreditation</u>

Findings:

• Based on staff perceptions, OTPs appeared to benefit from pursuing accreditation.

• Overall, study participants generally offered positive appraisals of accreditation, with 74% of site directors and staff agreeing they would rather work in an accredited program.

• A little less than half (43%) of OTPs agreed that since accreditation, treatment plans were better and the treatment environment was better (44%).

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• Fewer than half–43% –of all OTPs said they found the process of accreditation to be burdensome

Discussion: Implementing an accreditation-based regulatory system within opioid treatment represents a monumental shift from the previous approach to oversight under the FDA. Generally, accreditation activities are often perceived as administratively demanding, and it was anticipated this might be even more the case given the complexities inherent to health care organizations such as opioid treatment programs.

The support and commitment of treatment staff during such an endeavor is critical to successful outcomes; and the perceptions of staff can play a critical role in framing a supportive environment conducive to implementing change. The findings of the Evaluation Study indicate that overall, staff viewed undergoing accreditation as a positive experience, and one that improved the treatment environment.

Costs of Accreditation[6]

Findings:

• Based on findings from the Impact Study, average total site costs of preparing for and undergoing accreditation were $48,005 per OTP. Of this amount:

-Site preparation costs accounted for 82% of the total
-Technical assistance costs, for 7% of the total (SAMHSA paid these costs for study participants.)
-Accreditation survey fees: 11% of the total (SAMHSA paid these costs for study participants.)

• The total cost of preparing for accreditation was not associated with ownership, size, urbanicity, or organizational structure (i.e., being part of a parent organization).

• The majority of accreditation preparation time went to updating policy and procedures, holding staff meetings, and conducting training. The largest portion of the nonlabor costs went to upgrading facilities ($3,476).

• Across OTPs, 99% reported undertaking some level of activity in preparing for accreditation and 91% reported using technical assistance to prepare for accreditation.

Discussion: Little research exists on the costs of accreditation in any field. The few existing articles focus on accreditation costs for hospitals and educational institutions, and costs are often cited as a major concern of the accreditation process. Because accreditation is new to the opioid treatment field, no earlier research exists on the costs incurred by OTPs pursuing accreditation. The Impact Study represents the first time that a systematic economic approach has been applied to evaluating the total economic costs and activities involved for OTPs associated with pursuing accreditation.

One obvious finding was that the costs of achieving accreditation extend beyond the fees associated with the accreditation survey. In fact, the fees represent only a small part (11%) of the financial burden to programs undergoing accreditation. Most preparation involves personnel costs and time, a greater concern for smaller programs. Typically, the accreditation process involves months spent by program staff

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[6] Cost data were collected for 102 sites that underwent accreditation surveys as part of the Impact Study. For a variety of logistical and methodological reasons, complete and accurate follow-up cost data could not be reasonably collected within the timeframe of the study to allow a fair assessment of the change in costs associated with accreditation.

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preparing the site to comply with accreditation standards, followed by a survey visit from the accreditation organization. In many cases, those initial months of preparation may consume the majority of resources the site spends in the accreditation process.

In a cost analysis of *anticipated* expenditures associated with accreditation conducted by the National Committee for Quality Assurance (NCQA) for managed behavioral health care organizations (MBHOs), it was estimated that only about 13 percent of survey-specific expenses would be for the actual survey visit. The remaining 87 percent would go to preparing for that survey, including the accreditation assessment, staff training, revision of policies and procedures, and undergoing a "mock survey." Similarly, findings from the Impact Study indicated actual preparation costs far exceeded fees.

The findings from this study support the expectation that direct labor costs account for the majority of the total cost of pursuing accreditation. Also, these costs did not differ based on organizational ownership, size, or location. Additionally, it can be noted that DHHS originally estimated that the average cost to OTPs to meet accreditation standards would be considerably less than was estimated in this study. DHHS also estimated that only 25% of OTPs would require improvement to come into compliance with accreditation standards, whereas findings from the Impact Study indicate that most sites needed and used technical assistance in pursuing accreditation. It can be argued that first-time costs of engaging in an unfamiliar process might be expected to exceed expectations. In addition, comments from program staff suggest that in the context of the study, some 'reframed' costs as being accreditation-related were otherwise considered more routine. Also, the apparently high costs and use of technical assistance by so many programs may simply validate the initial impression of the need (and desire) for overall improvement that led to the shift to accreditation, and if anything may suggest that the need was far greater than first realized. Importantly, programs sought, used and benefited from the technical assistance when made available.

Impact of Accreditation on Treatment Services

A critical precursor to the shift in regulatory oversight to an accreditation system was the variability in treatment effectiveness found across OTPs. With the development of the CSAT Accreditation Guidelines and the resulting accreditation standards, opioid treatment providers have now been given clear guidelines for care across 19 different domains. These domains span the areas of organizational administration, professional staff credentials and development, patient admission criteria and assessment, treatment planning, unsupervised approved use, special populations, patients' rights, and diversion control. The anticipation has been that shifting oversight of opioid treatment programs from the regulatory structure under the FDA to an accreditation-based system under SAMHSA oversight would increase the flexibility of clinical judgment within the OTP, promote accountability, strengthen performance measurement systems, and ultimately improve the quality of services provided to OTP patients.

In the section that follows, findings are presented on the impact of accreditation on organizational, staffing, and patient characteristics; the comprehensiveness of services offered to patients; clinicians' flexibility to exercise professional discretion concerning such treatment issues as dosing and time in treatment, and the utilization of performance measurements within the OTP.

Changes in Organizational, Staff, and Patient Characteristics

During the development of the final regulation, public concerns were raised that an accreditation system would negatively affect treatment capacity, in that a number of OTPs would be unsuccessful in achieving accreditation. Therefore, the Impact Study examined the impact of accreditation on treatment capacity. Additionally, under the oversight of SAMHSA, OTPs undergoing accreditation are accountable for the treatment areas of patient assessment, patient diagnosis, staff certification, staff training, emergency

access, and diversion control. Each of these areas represents a critical component of opioid treatment and thus was also examined in the study, as highlighted in the following.

Finding:

• Findings indicated no diminution in treatment capacity. In fact, increases in patient capacity were reported by sites that underwent accreditation as well as those that did not, within the time frame of the study.

• In terms of emergency access, results suggested an overall trend toward greater use of 24-hour workers and pagers or cellular telephones, and more so by sites that underwent accreditation than by sites that did not. Emergency access rose from approximately 21% to 29% of programs that underwent accreditation, and fell among programs that did not (from 19% to 11%).

Discussion:

Overall, accreditation did not lead to the loss of treatment capacity anticipated by some key stakeholders, and potentially may have contributed to improved access in existing OTPs. Given that this overall trend extended to programs that did not undergo accreditation, this suggests that either the trend did not 'result from' accreditation but was also not diminished by accreditation; or was potentially driven by the influence of 'accreditation on the horizon').

Findings:

• Staff retention increased significantly at sites that underwent accreditation compared to those that did not, suggesting that accreditation may promote staff retention. However, staff turnover was noted as an issue by 18% of the sample.

• Sites that underwent accreditation offered significantly more training opportunities upon follow-up than did sites that did not undergo accreditation.

• Many OTPs were undergoing significant change even before accreditation was implemented. Just over 40% reported a major change (new ownership, new site or site director, or new approaches to treatment) in the preceding 6 months.

• Length of time in continuous treatment at the same program was reported as between 1 and 2-years by 21% of patients and more than 2-years by 41% of patients.

Discussion:

Findings from this study, structured so as to provide a representative sample of patients and sites, suggest that retention, an accepted indicator of successful outcome, is greater than has been reported in research studies that have drawn their samples from the subset of more severely dependent patients. To date, most clinical research studies of opioid treatment have not involved a representative sample of sites with proportionate representation of both for-profit and non-profit OTPs.

Finding:

• Patient assessment did not change at sites undergoing accreditation. At both baseline and follow-up, patients were assessed using a variety of instruments, with the most common being program-developed.

Discussion:

Continued variability related to patient assessment and staff certification suggests that OTPs need further guidance and assistance to better address these areas. These findings are supported by the accreditation standard findings, which indicated that two domains, screening and assessment/diagnosis and organizational administration, received the highest number of citations. Many OTPs reported using assessment instruments they themselves developed. Creation and utilization of unique screening, assessment and monitoring tools suggests either a lack of knowledge about the standard tools already available or a discomfort in using such tools.

Recommendation:

Accreditation standards, SAMHSA accreditation guidelines, and professional publications should continue to promote the use of performance measures and to support staff development and the importance of using established tools for screening, assessment and diagnosis.

Finding:

- The percentage of staff with some form of substance abuse certification (CDAC, CADAC, CAC, and state certifications) was relatively low both at baseline and follow-up (pre- and post-accreditation).

- The most commonly required certification for counselors by sites at both baseline and follow-up was state certification.

Recommendation:

Program sponsors, administrators and clinical supervisors should invest in career advancement of their professional staff by encouraging and funding certification and licensing and in general, by promoting advanced specialization within the field.

Findings:

- Accreditation did not appear to lead to an increase in methadone diversion in the short term.

- Also, no increases in diversion were noted at sites that did not undergo accreditation.

- Few sites reported a thorough approach to diversion control as would have been indicated by the inclusion of a diversion control plan.

Discussion:

A concern of some stakeholders, in anticipation of the shift to accreditation, had been that what were perceived to be looser guidelines for take-home medications might lead to increased methadone diversion. Findings suggest this was not the case. At the same time, at least within the study timeframe, accreditation did not yet lead to wider adoption of stronger diversion control measures.

Overall discussion:

The Impact Study found no impact on treatment capacity as a result of undergoing accreditation. Additionally, no increases or decreases in diversion occurred as a result of undergoing accreditation. Staff

retention and emergency access were reported as improving after undergoing accreditation. Both patient assessment and staff certification were highly variable across OTPs at baseline; and even after undergoing accreditation these OTP characteristics remained unchanged.

Changes in Comprehensiveness of Services

Findings:

• Overall, non-profit/public and larger sites offered a significantly greater number of core services (dosing, medical care, counseling) than other sites. Also, non-profit/public and larger sites offered significantly more of these services onsite or through another of their program's sites.

• Upon follow-up, sites that underwent accreditation offered significantly more comprehensive services than did sites that did not undergo accreditation.

Discussion:

The positive impact of offering an array of services in addition to methadone dosing services has been well documented. The benefits to patients in methadone maintenance treatment from individual counseling, group counseling, medical services, psychological services, and other ancillary services (e.g., child care, transportation, housing, legal) have been well established. Both the SAMHSA Accreditation Guidelines and the accreditation standards developed by CARF and JCAHO promote the inclusion and use of comprehensive services. It is possible that this focus on comprehensive services may have promoted an increase in these services at sites that underwent accreditation under the Impact Study. In any case, study findings suggest that accreditation may improve the comprehensiveness (and hence, quality of care) available to patients. To determine whether this effect is sustained in the long run would require longitudinal study.

Recommendation:

OTPs should continue to expand on-site services to patients, including both core and ancillary services; if programs are not able to offer on-site services, referrals should demonstrate effective follow-through.

Changes in Professional Discretion

Findings:

• The average maintenance dose was slightly higher upon follow-up than at baseline, both at sites that underwent accreditation and those that did not. Specifically, the average maintenance dose of about 69 mg./day rose to about 72 mg./day. This confirms other recent studies concerning dosing practices.

• The proportion of patients having three or more take-home privileges upon follow-up did not differ significantly between sites that underwent accreditation and those that did not.

Discussion:

The shift to an accreditation system was anticipated to offer more flexibility to clinicians in OTPs, by allowing a higher level of professional discretion to be exercised in decision-making about dosing, unsupervised approved use, time in treatment, and other patient care areas. This study found that little change in terms of clinical judgment or decision-making was reported between baseline and follow-up, regardless of whether a site underwent accreditation. This is better understood in the light of baseline

findings which indicated that, despite the prescriptive nature of the regulatory system under FDA (in other words, long prior to the shift to accreditation), professionals within the opioid treatment system had already found varying ways to exercise their professional discretion.

Impact Study findings also suggest that best practice literature regarding dosing is gradually being synthesized and implemented by treatment programs, an influence shared by programs whether or not they underwent accreditation. Across the board, regardless of whether they underwent accreditation, OTPs reported a slightly higher average maintenance dose upon follow-up than at baseline. However, neither sites that underwent accreditation, nor those that did not, reported using the more flexible "take home" schedules allowed by the new federal regulations.

Changes in Performance Measurement

Findings:

> • Within the Impact Study, 74% of site directors reported that accreditation had an influence on the monitoring of patient outcomes, with 70% reporting that accreditation would affect their current quality assurance system, requiring the addition of new procedures.

> • Compared with programs that did achieve accreditation, OTPs that did not achieve accreditation on the first survey reported that they had to exert more effort to put into place the mechanisms required by accreditation to maintain quality treatment (for instance, monitoring of patient outcomes, implementing new quality assurance procedures, and more thoroughly documenting patient progress).

> • Small and nonurban OTPs were less likely than urban and large urban sites to track patient outcomes or the effectiveness of quality assurance processes.

Discussion:

Historically, performance measurement activities have played a limited role in opioid treatment programs. Moving oversight of OTPs from regulation under the FDA to an accreditation system overseen by SAMHSA was anticipated to improve services provided to OTP patients. In particular, the quality assurance and performance measurement requirements incorporated in the CSAT Accreditation Guidelines and accreditation standards were anticipated to increase OTP accountability and to strengthen continuous quality improvement efforts. For instance, accreditation has heightened focus on the development and implementation of appropriate outcomes management systems within OTPs, which are intended to increase accountability and performance measurement activities. Findings from the Impact Study indicate that site directors perceived accreditation as affecting current quality assurance systems in various ways, for instance requiring the addition of new procedures. Small and nonurban OTPs reported having a more difficult time implementing outcomes management systems than did urban and large-urban OTPs.

Recommendation:

SAMHSA, professional organizations, opioid practitioners, and accreditation bodies should work together to develop consensus on performance indicators to be included in OTPs' continuous quality improvement plans. Development of these indicators should take into account administrative differences among programs and the more limited resources of small and rural OTPs.

CASE STUDY:
EXAMINING THE ROLE OF STATES UNDER AN ACCREDITATION SYSTEM

Regulatory analysis and case studies of opioid addiction treatment as conducted in Indiana, Massachusetts, North Carolina, Nevada, and New York allowed evaluators to identify a number of concerns shared by States related to operating under an accreditation system. For purposes of this study, these were collapsed into nine categories: 1) oversight, 2) quality, 3) access, 4) communication, 5) geographic differences, 6) outcomes, 7) technical assistance, 8) administrative burden, and 9) standards. The findings which follow are organized by these categories.

Respondents in the State Study welcomed the opportunity to discuss issues regarding opioid treatment, as well as accreditation in specific. Their comments reflected a great deal of confusion and misunderstanding regarding accreditation. Some of the concerns they raised were rooted in an as-yet incomplete understanding of accreditation; others spoke to challenges in the treatment field more generally.

It should be noted that the findings discussed here are not limited to accreditation, and some may be well outside the purview of the Federal government to address. In any case, it is clear that accreditation has placed a spotlight on the entire opioid treatment system.

Findings:

Oversight
- State respondents expressed a variety of opinions and observations concerning the effect of accreditation on State oversight of OTPs. Some respondents thought that accreditation would reduce State involvement; others, that it would lead to a tightening of State regulations. Several respondents expressed the need for State oversight to be consistent with federal requirements, given that programs must comply with State and Federal regulations.

- Other respondents indicated some concern with the specific qualifications of accreditation surveyors.

Quality
- These respondents expressed concern with the patient grievance procedures established under the accreditation system. Prior to accreditation, patients reported complaints and concerns to their State Methadone Authority (SMA). Officials worried that patients might not call upon accreditation bodies in the same way.

- Respondents raised concerns that accreditation may not necessarily ensure quality treatment throughout the accreditation cycle. For instance, some respondents were concerned about whether programs would *maintain* quality care between accreditation surveys.

Access

- Respondents raised several concerns about the cost of accreditation and how this might affect treatment capacity. A related issue was the potential for OTPs to increase patient fees to off-set accreditation-related costs.

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Communication

• States expressed concerns related to maintaining ongoing communication among accreditation bodies, SAMHSA, and State authorities.

Geographic Differences

• Some respondents stressed the special needs of geographically isolated areas and the OTPs operating in rural or nonurban areas. They expressed concern that the challenge of addressing accreditation may negatively affect the continued operation of rural and nonurban OTPs.

Outcomes

• Respondents held an array of opinions surrounding opioid addiction and its treatment, reflecting little consensus on the intended outcomes of opioid treatment.

Technical Assistance

• Several respondents expressed the belief that technical assistance for OTPs would continue to be needed to facilitate the success of a national accreditation system.

Administrative Burden

• The administrative burden to OTPs associated with operating as accredited programs was highlighted as a critical concern among States; and several expressed the fear that the administrative burden associated with pursuing and maintaining accreditation would negatively affect patient care.

Standards

• Several respondents expressed concern regarding specific accreditation standards that they believed would be difficult for many OTPs to address, potentially resulting in their being cited for noncompliance.

CONCLUSIONS

Several of the findings from The Opioid Treatment Program (OTP) Accreditation Impact Study, 1998-2002, hold implications worth further consideration, not only by SAMHSA but also the accreditation bodies, researchers and practitioners in the field of opioid treatment, patient advocacy organizations, policy-makers, and professional and trade associations active in this area.

An important global implication of the Impact Study is the need for all parties to come to consensus concerning protocols and tools to be used to carry out routine but critical functions. Study findings suggest these would include at the minimum, assessment tools and treatment planning protocols, dosing, monitoring tools, diversion control policies and procedures, and indicators of quality service delivery. The SAMHSA Treatment Improvement Protocol (TIP) and consensus statements have proven effective and SAMHSA can ensure these continue to be improved and updated as our knowledge about treatment expands. As the field of opioid treatment grows, so too will its needs. These changes need to be incorporated into planned revisions of the SAMHSA accreditation guidelines.

Additionally, as new pharmacotherapies, such as buprenorphine, are approved and integrated into OTP settings, new accreditation guidelines and best practices may also be developed to promote continued comprehensive, quality treatment. This too is an area about which all stakeholders should continue to work together in the joint goal to promote current and comprehensive care for opioid patients. For instance, recently developed best practice guidelines (promulgated through SAMHSA/CSAT's Treatment Improvement Protocol publications), Federal standards, and accreditation standards require systematic review and oversight to ensure the continued provision of quality care. Review of guidelines should continue to incorporate the perspectives of all stakeholders in this process, including regulators, researchers, policy-makers, practitioners, patient advocacy organizations, and representatives from the accreditation bodies. Future revisions to guidelines may draw upon findings from this study, a new SAMHSA study of accreditation that commenced in 2002, and other, ongoing, clinical research on dosing, comprehensiveness of services, and assessment.

Several findings from the Impact Study helped identify particular areas that OTPs need assistance with in their efforts to achieve and, also, maintain, accreditation. Overall, OTPs received minimal standard citations in the methadone treatment practice areas of medication use, dosing, take-home dosing, and drug screening. On the other hand, accreditation outcome findings showed areas in which OTPs were having the most difficulty coming into compliance with standards–namely, those falling under the domains of organization/administration, staffing and assessment, and performance improvement. For instance, although success in accreditation was associated with better staff retention, that remained an issue for a large number of programs.

Importantly, estimates derived from this study suggest that the costs of accreditation were higher than projected when the Notice of Proposed Rule Making was published. This increase was largely related to the global need of OTPs to prepare staff for accreditation. This widespread need to 'come up to speed,' at least in this first round of accreditation, may well be seen as validating the original concerns for the need to enhance treatment quality, which led to the shift to accreditation to begin with. These findings also suggest that OTPs–with special attention to smaller OTPs and OTPs in more isolated areas–may require some on-going financial or technical assistance support as they continue to transition into the accreditation system. As found in the study, programs needed but also welcomed technical assistance in meeting the demands of the new system and, it is likely, may require at least some continued assistance until the transition is completed.

The study pointed to some important developments that may change our assumptions about opioid programs and patients. For one, for-profit programs are playing an increasing role in the field of opioid

treatment. In addition, the study pointed to changes in this patient population that should be of interest and may demand the attention of SAMHSA and stakeholders in the field of opioid treatment. For one, OTP patients are becoming older and their psychosocial and medical needs, more complex–yet another argument for well-trained staff and comprehensive services. Half of patients in this study were employed, perhaps a larger proportion than might have been expected. Patient retention, an accepted indicator of successful outcome in this study, exceeded what has been reported in research studies that have drawn their samples from a subset of more severely dependent patients. What was not noted in the data collection timeframe of this study but which has colored the landscape of opioid treatment in some localities across the country has been the increasing numbers of patients seeking treatment for addiction to prescription opioids such as OxyContin, a population that will potentially add to the diversity of what we think of as 'opioid dependent' individuals.

Conclusions that can be made at this point about the changes wrought by accreditation must be considered somewhat conservative; given the narrow time frame available for the collection of follow-up data (generally, six months although in some cases, several months longer). The field of opioid treatment will benefit greatly from the continued evaluation of treatment practices and the affect of accreditation on these practices. For that reason, SAMHSA continues to monitor developments in the field and to this end has embarked upon a new study, "Evaluating the Impact of Opioid Treatment Program Accreditation, 2002-2005." The new study is examining many of the same issues as this first study, but at a point when accreditation has become mandatory for all programs; also, the new study will consider the impact and costs related not only to achieving but also, maintaining, accreditation.

Ultimately, despite the usual study limitations, findings from the Impact Study support the Federal government's decision to move to a new, accreditation-based regulatory model. While it is premature to assert that the new accreditation system has yet achieved the expectations of improving quality of care and reducing variability in the standard of care provided, there are signs–hopeful signs– that changes are taking place which, if properly nurtured, will lead to positive outcomes without reducing treatment capacity.

APPENDIX A. THE ACCREDITATION PROCESS AND ACCREDITATION OUTCOMES

Between 1998 and 2002, JCAHO and CARF conducted 130 accreditation surveys of opioid treatment programs (OTPs). The initial group of 172 OTPs was selected in a stratified random sampling process. This number was further subdivided into experimental and control groups for purposes of the study. The accreditation surveys of OTPs in the control group were delayed until after accreditation surveys for the experimental group had been completed. Approximately 26 of the OTPs dropped out or were unable to participate further in the study, and a number of control sites chose to delay accreditation until after the project had ended. However, by 2004, all of the OTPs in the original study had become accredited.

To be accredited, an OTP must meet the standards established by the accreditation body that surveys it. Because an OTP may not meet every applicable standard, the accreditation decision is usually based on scoring the OTP on its strengths balanced against those areas in which the OTP needs improvement. The score assigned to each of these standards and the number of standards cited result in the overall score that an OTP receives. They range from CARF's nomenclature of "Non-accreditation," "Three-month abeyance," "One-year Accreditation," or "Three-year Accreditation," to JCAHO's nomenclature of "Preliminary Non-accreditation," "Conditional Accreditation," "Accreditation With Type I recommendations," or "Accreditation Without Type I recommendations."

Based on experiences during the OTP accreditation project, both accreditation bodies have observed that many OTPs are capable of preparing for accreditation within a 6-month period. On the other hand, the accreditation bodies also recommend that OTPs prepare for accreditation over a longer period of time in a measured, methodical and deliberate fashion. Optimal preparation time, depending on the organization's complexity and resources, may take 12 months to two years. Accreditation preparation takes a lot of time and effort because it frequently requires OTPs to make significant changes to the systems of patient care. These systematic changes may involve paying special attention to monitoring patient outcomes, adopting procedures to convey respect for consumers, improving the efficiency of procedures, reducing risks to patients and the organization, ensuring that staff are competent, recruiting the proper mix of disciplines and providing for sufficient numbers of staff.

Listed below the accreditation standards most frequently cited in seven of the most difficult to meet domains identified by JCAHO and CARF during the impact study project.

Leadership

- The leaders understand performance improvement approaches and methods. The leaders communicate appropriate information about strategic and other plans throughout the organization.

- Administrative and clinical leaders collaboratively establish necessary structures, bylaws, rules, regulations and processes to support clinical activities.

- Clinical leaders participate in determining the qualifications (training, experience and documented competence) required for staff assuming specific clinical service responsibilities.

- The leadership of each program or service is effective. The leadership is responsible for establishing accountability to the governing body.

- The leadership is responsible for developing and implementing policies and procedures that guide the provision of services.

- The leadership is responsible for orientation, in-service training, and continuing education of all persons in the program.

- The leaders set expectations, develop plans, and manage processes to assess, improve and maintain the quality of the organization's governance, management, clinical, and support activities.

Outcomes Measurement

- The organization collects data to monitor its performance. Outcomes and processes should be measured and monitored such as reducing or eliminating the use of illicit opioids, illicit drugs, and the problematic use of licit drugs; reducing or eliminating associated criminal activities; reducing behaviors contributing to the spread of infectious diseases, and improving quality of life by restoration of physical and mental health and functional status.

- The organization collects data to monitor improvements in performance and the data are systemically aggregated and analyzed on an ongoing basis.

- The planning process provides a framework for setting performance improvement priorities and identifies how priorities are adjusted in response to unusual or urgent events.

- The organization should demonstrate that the information collected is used to improve the quality of its services.

- The organization's expectations regarding outcomes should be clearly described in the program's measurable objectives.

- The outcomes management system should include program description, measurable objectives in the areas of effectiveness, efficiency, consumer satisfaction, and use of results.

- The organization should measure outcomes before, during and after treatment.

- Outcomes measures should assess efficiency measures such as access and appropriateness.

Management Planning

- The organization should show evidence of an organized system of information management that includes use of information for decision-making.

- The management plan should address security, control of hazardous materials and wastes, emergency preparedness, safety including regular emergency drills, medical equipment, and utility systems.

- The annual organizational plan for performance improvement should be developed. This plan should describe the ongoing planning process and include a description of an organized information management system, the results of the needs assessment process, the quality

assessment process, an outcomes management system, and evidence of how the findings are incorporated into other plans, disseminated, and used for performance improvement.

- The organization should develop a management report at least annually. The management report should describe, analyze, and summarize the results of the program plans, including the population served, the admission criteria, the community needs assessment, the quality assessment, the goals and objectives. The data should be collected in the areas of effectiveness, efficiency, consumer satisfaction and analysis of the use of results.

- The management report should be made available to a variety of audiences.

Human Resources and Training

- The organization should develop job descriptions for all staff members that include expectations regarding quality and quantity of work, have reviews that are dated and conducted regularly for continuing appropriateness.

- Personnel policies should be regularly updated as needed.

- The organization should conduct a job performance evaluation for each staff member at least annually. The evaluation should include an assessment of job performance in relation to expectations set forth in the job description, a comparison to the last performance evaluation, and establishment of performance objectives for the next evaluation period.

- The organization should demonstrate personnel development practices that include provisions for periodic assessments of the training needs of all personnel.

- Staff qualifications are commensurate with anticipated job responsibilities and applicable licensure, law and regulation, registration, and/or certification.

- The organization provides an adequate number of staff members whose qualifications are consistent with job responsibilities.

- Competence of all staff members is continuously assessed, maintained, demonstrated, and improved and begins with an orientation process for initial training and information.

- Ongoing education and training maintain and improve staff competence.

- There should be annual training for all staff members on the prevention of violence and the management of unsafe behaviors, confidentiality requirements, and cultural sensitivity.

- The organization continuously collects and aggregates data regarding staff competence patterns and trends to identify and respond to staff learning needs.

- The organization assesses each individual's ability to meet performance expectations, as defined in delineated clinical privileges and/or job descriptions.

- The organization has a process to ensure the competence of licensed independent practitioners including initial assessment and on-going competence that includes a review of licensure, certification or registration.

- There is a fair hearing and appeal process for addressing adverse decisions about granting, renewing, or revising clinical responsibilities for licensed independent practitioners.

- Competence of providers who are not independent practitioners is ensured by initial assessment and periodic reassessment.

- The organization should conduct a professional review of the services provided. The review should address the quality of services, the appropriateness of services, and the use of services.

- A quarterly professional review should be conducted of a representative sample of both current and closed records.

- The professional review should address whether the assessments of the persons served were thorough, complete, and timely. Also it should address whether the service goals and objectives of the persons served were based on the results of the assessments, the actual services were related to the service goals and objectives and that the persons served were actively involved in making informed choices regarding the services they received.

Assessment

- Assessment data are analyzed and integrated to identify and prioritize the individual's care needs.

- Diagnostic testing is performed to determine the individual's health care needs and as part of care.

- Care decisions are based on the individual's identified needs and care priorities.

- Assessment and reassessment of individuals receiving treatment addresses cultural orientation, sexual preference and religion and spiritual orientation.

Treatment Planning

- Treatment planning identifies care and services appropriate to the individual's specific needs.

- The treatment plan reflects the individual's clinical needs, condition, functional strengths and limitations.

- Individuals are encouraged to participate in developing their treatment plans, and their involvement is documented.

- The treatment plan contains specific goals related to achieving emotional and/or physical health as well as maximum growth and adaptive capabilities.

- Treatment planning identifies care and services appropriate to the individual's specific needs and the severity of condition, impairment or disability. The treatment plan includes specific objectives for the goals identified in the plan.

- The treatment plan specifies the interventions and approaches necessary to meet the individual's needs and goals.

Discharge Planning and Follow-up

- A discharge summary reviews the reason for treatment or services, the significant findings, treatment or services provided, the individual's condition on discharge, and any specific instructions given to the individual and/or family, as appropriate.

- A written plan on input from the persons served that includes how the organization annually obtains input from the persons served, how the input is reviewed, and how the input is used to change the practices or policies of the organization.

- The organization should collect post-discharge outcomes information from at least 10% of the persons served. It should include a) making necessary arrangements with the persons served as well as other organizations and individuals to insure a high contact rate, b) collecting clinical information that compares the current status of the persons served their status at discharge, c) incorporating the measurable satisfaction of the persons served into the outcomes system.

- Follow-up should also include the provision of assistance in determining whether further services are needed, the determination of persons served who are considered at risk, compliance with the applicable state, provincial, and federal guidelines regarding confidentiality.

- A discharge plan should be prepared for each person. The plan should include the input from the person served, the family or legally authorized representative, when appropriate, and the referral source, as appropriate. The discharge plan should include the strengths, abilities, needs, and preferences of the person served and describe the preferences and expectations established and achieved.

- The discharge plan should be developed at the earliest possible point in the service delivery process.

Appendix B. TECHNICAL ASSISTANCE PROJECT FOR OPIOID TREATMENT PROGRAMS: PREPARING FOR ACCREDITATION DURING THE IMPACT STUDY

Between 1998 and 2002, CSAT worked with one contractor to deliver technical assistance (TA) to opioid treatment programs (OTPs) seeking to achieve accreditation. Under the OTP Accreditation Impact Study, the contractor vigorously marketed accreditation TA and provided 5 types of TA to programs requesting assistance to prepare for CARF or JCAHO accreditation surveys--

- Initial onsite assessments (for all programs),
- Targeted follow-up TA (onsite or offsite),
- Specialized training,
- Resource materials, and
- Onsite practice surveys (requiring clinical and administrative expert consultants).

During the Impact Study, the contractor provided for—

- TA to 131 programs in the experimental group of the impact study (83 for CARF and 48 for JCAHO);
- TA to 28 OTPs in the control group that had delayed accreditation surveys (15 for CARF and 13 for JCAHO);
- 818 consultant days (514 for CARF, 65 for JCAHO) and 178 trips to conduct the TA;
- TA and logistical support at 45 meetings with a total of 1,573 participants;
- 470 meeting trips (352 participant and 118 consultant trips).

Only 13 of the 172 OTPs identified for the impact study declined to accept TA, and some OTPs dropped out of the study. On average, programs in the CARF study required 3 consultant days for onsite assessments; JCAHO programs required 4 days. These consultant days included time for report preparation. Approximately 18 percent of the programs received 2 to 4 days of onsite and offsite TA after the assessment; 7 percent received more than 4 days. The number of TA days used by the programs ranged from 0 to 15. TA costs averaged $3,000 per OTP.

Lessons Learned

The TA delivery process revealed that the contractor's original concepts about the TA project did not always match the OTPs' actual needs. Early in the TA process, consultants learned that programs were having difficulty shifting their operational perspective from regulatory compliance to comprehensive quality of care. This need to shift perspectives affected how programs were developing their plans and procedures to meet accreditation requirements. Staff members in the Division of Pharmacologic Therapies found that it was important for programs to understand why a shift to comprehensive quality of care was necessary and what this shift meant to programs. Helping OTPs understand the shift and its impact led consultants to place less emphasis on the traditional compliance approach to treatment and to stress a more holistic approach--the essence of behavioral health care standards.

This approach involved—
- educating OTP management and staff about the overarching concepts and principles of effective patient care practices using didactic and hands-on approaches;

- de-emphasizing rote compliance with individual rules, regulations or standards; and

- moving OTPs away from "cookbook" approaches to compliance and into on-going deductive and inductive reasoning processes.

For example, OTPs were taught that just having a written plan for using patient satisfaction surveys and other feedback to periodically assess and modify treatment was not adequate. What OTPs had to demonstrate to accreditation surveyors was that this plan was actually implemented, that OTP staff members—

- actually met on a regular and on-going basis,
- examined and discussed the results of satisfaction surveys and other types of patient feedback,
- discussed and modified treatment in light of this feedback,
- documented these changes in meeting minutes and in policies and procedures,
- documented changes in treatment approach in patient records; and
- followed up by repeating the procedure, eliciting patient feedback, analyzing this feedback, and documenting changes to the treatment program.

TA consultants educated OTPs that accreditation surveyors were looking for organizational systems that identified potential problems or areas that needed improvement and modified these systems, monitoring outcomes to make sure that changes actually resulted in improved outcomes. The goal was to produce a system that continuously modified, corrected and improved itself.

At the beginning of the study, it was assumed that OTPs generally were expert at providing appropriate care, but were not skilled with documenting policies and procedures or care-delivery in patient records. The original TA design focused on document review, document development, improving patient records, and some targeted training. As the project progressed and as consultants learned that OTP staff needed to be led to make conceptual shifts to a more dynamic model of treatment, consultants refocused TA efforts on four areas—

- Creating plans for service (developing philosophies, mission statements, leadership, etc.);
- Creating documentation (understanding the relationships between the required documentation and the standards);
- Illustrating the relationships among standards; and
- Integrating performance measurement and performance improvement.

Near the end of the study, SAMHSA informally polled the OTPs regarding technical assistance. Although this poll was not scientific, it was interesting to learn that OTPs, by far, rated the TA provided during this project as the most valuable support that SAMHSA had provided during the accreditation effort. When asked to recommend which supports continue if SAMHSA funding were to be reduced for the project, a large majority of the OTPs recommended that TA remain fully funded, because OTPs had found it to be invaluable in attaining accreditation. Other supports, such as paying OTPs' accreditation fees, were valued, but rated less highly.

Refining TA Delivery

DPT learned that the level of effort and costs involved in providing TA to programs pointed to a need to streamline the TA delivery process whenever possible. At the same time, the contractor did not want to sacrifice the quality or depth of TA; therefore, several approaches were used to provide effective, cost-efficient TA—

- **Targeted statewide trainings:** The contractor planned and conducted 4 working seminars for programs in California, Florida, Texas, and New York that were involved in the impact study.

- **One consultant/one program; One consultant/one State; One consultant per large organization:** To ensure continuity of TA delivery to each program, the contractor made an effort to assign a single consultant to a program, a state or a large organization whenever appropriate and feasible. The same consultant was assigned to work with many of the programs in a State and within large organizations throughout the TA process. This approach minimized the learning curve for consultants for each TA assignment, and also tended to reduce the need for several onsite visits, thus keeping travel and lodging costs to a minimum. This approach permitted consultants to consistently convey the same or similar messages and to communicate effectively with OTPs in which personnel may have tended to interpret the standards differently or in those OTPs that were looking for ways to conform minimally with standards. The major exception involved practice surveys, for which it was deemed important for the program to be assessed by expert consultants who were not familiar with the program's TA history, thereby more realistically simulating the actual survey process.

DPT, the contractors, accreditation bodies and OTPs also realized that there was an absolute need for communication among the various government agencies, contractors, grantees and TA recipients involved in the study. This communication not only kept designated people aware of operational information but it also allowed for the examination of potential problem areas and aided in developing creative solutions for their resolution.

Appendix C. NOTE FROM RTI ON CONTRIBUTORS TO THE OPIOID TREATMENT PROGRAM ACCREDITATION IMPACT STUDY