Evaluation of the Buprenorphine Waiver Program

Buprenorphine Reimbursement and Availability Tracking Study

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FINAL REPORT

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1. INTRODUCTION AND CONTEXT

The Buprenorphine Reimbursement and Availability Tracking Study, which was performed from the first quarter of 2004 to the first quarter of 2005, was a component of the Evaluation of the Buprenorphine Waiver Program. The Tracking Study examined the actions, decisions, and questions of key decision makers in organizations in the payment and distribution channels of the health care and substance abuse treatment systems. The purpose of this study was to establish a baseline and monitor trends in actions by decision makers in these organizations regarding the dissemination and adoption of buprenorphine, both as a medication and as a new medication-assisted treatment for opioid dependence and abuse. The study was based on four waves of semi-structured interviews with key informants from organizations throughout the purchasing, payment, and distribution systems for buprenorphine. These included drug distribution companies, health plans, managed behavioral health care organizations, state substance abuse and Medicaid systems, organized care systems, pharmacy benefit managers (PBM's), pharmacy associations that represent pharmacists, and retail pharmacies.

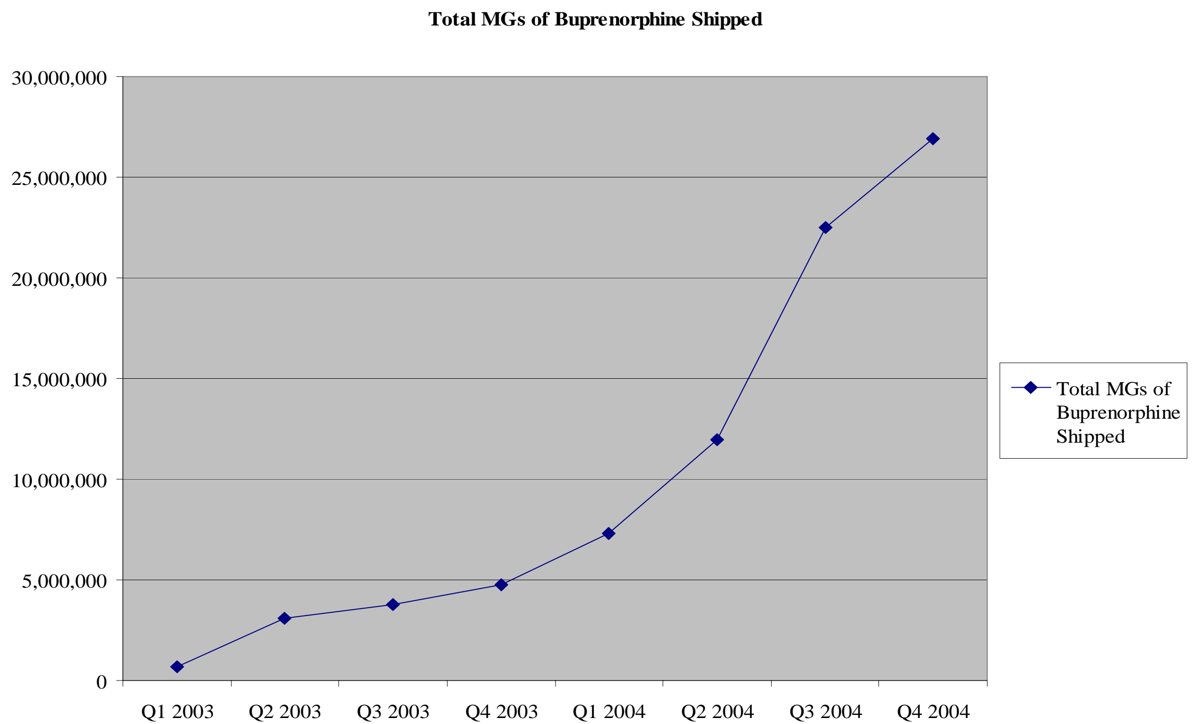
The study focused on decision making in the system of distribution and payment for opioid dependence treatment with buprenorphine (Subutex® and Suboxone®). A New Drug Application (NDA) for Subutex® was submitted to the FDA in March 1997 and an NDA for Suboxone® was submitted in June 1999. Both NDAs were approved in October 2002; the approval processes for both medications took longer than the average time for approval noted by Carpenter et al. (2003) during the 1997-2000 period.[1] The approval timeframe delayed launch of the medication until January 2003.

The medication distribution and payment system includes pharmaceutical distributors and wholesalers, as well as the retail pharmacies, clinics, and other health care and substance abuse treatment facilities that they supply. The system also includes PBMs that provide outsourced formulary assistance and drug utilization management to public and private sector purchasers, insurers, organized care systems, and health plans. Direct payers, including both large public and private sector health plans and organized care systems, are also components of this system, as are state substance abuse systems, Medicaid, Medicare, and other government-sponsored health care programs. Decisions by these organizations helped to determine whether or not office-based physicians and substance abuse outpatient treatment programs provided buprenorphine treatment, whether or not pharmacies ordered and stocked the

[1] D. Carpenter, M. Chernew, D. Smith and A.M. Fendrick, "Approval Times for New Drugs: Does the Source of Funding for FDA Staff Matter?", Health Affairs, Datawatch, Web Exclusives, July-December 2003.

medication, and whether or not prospective patients who requested buprenorphine treatment from waivered physicians received it when clinically appropriate.

As reported by the Drug Enforcement Agency's Automation of Reports and Consolidated Orders System (ARCOS), shipments of buprenorphine (both Subutex® and Suboxone®) to opioid treatment programs, which began from a very low base during the first quarter of 2003, increased throughout 2003 and 2004. The quantity of buprenorphine shipped increased relatively slowly during 2003; both the quantities shipped and the rate of growth increased substantially during 2004.



Organizations that participated in the Tracking Study reportedly treated buprenorphine initially in the same way that any other newly introduced medication is treated. However, the introduction of buprenorphine was more complex because it was just one component of the introduction of a new modality of substance abuse treatment: office-based medication-assisted treatment. Although there had been a few demonstrations of office-based methadone treatment as past pilot projects, this was the first widespread initiative to extend the treatment of opioid dependence and abuse into physicians' offices. During the course of the Tracking Study, organizations involved in the substance abuse treatment

and reimbursement systems only gradually seemed to become aware of the challenges that accompanied such a transformation in the practice of substance abuse treatment. In these organizations buprenorphine "champions" sometimes emerged to promote use of the new medication when it became apparent to them, that simply making the new medication and treatment option available did not quickly lead to broad adoption and dissemination of this new treatment technology.

2. METHODOLOGY AND LIMITATIONS OF THE TRACKING STUDY

The Tracking Study consisted of four waves of semi-structured telephone interviews with key informants identified through a structured fact-finding process. The interviews provided a window into decisions about health care system-level, economic, and organizational factors that may have affected buprenorphine adoption and dissemination. Their goal was detecting places along the distribution and dissemination channels that may have had an impact on treatment approval, access, and payment. This small study complements the physician surveys and patient study components of the Evaluation.

The Tracking Study was a repeated, progressive description of structures and processes that may affect whether or not practitioners, clients, and payers can easily access buprenorphine. The periodic repetition of the interviews allowed an examination of trends in approval and reimbursement policy. It thus provided an overview of the adoption and dissemination of buprenorphine as a medication-assisted treatment from the perspective of the health care reimbursement system and purchasers. Potential and current systemic barriers as well as avenues to dissemination and corresponding policy issues were identified.

It would be appropriate to be cautious about the representativeness of the identified barriers and avenues, given the procedures used to sample informants and the qualitative study design. Prospective key informants were identified through a series of chain-of-command interviews, then contacted and interviewed repeatedly via e-mail and telephone. No reimbursement of any kind was offered. Study recruitment involved the following:

- An evaluation of the prospective informant's position as a decision maker or a staff relationship to such a person, as well as access to the information needed;
- Willingness to participate in periodic, half-hour telephone interviews for two years; and
- The geographical location and the place in the distribution and reimbursement system of the organization.

Every effort was made to select knowledgeable informants and to vary the organizations selected geographically. Nevertheless, the study is qualitative and descriptive. The selection of respondents was purposive, rather than random, as was the selection of the types of organizations. The informants may or may not have been fully representative of individuals within their organizations and

the organizations may not have been typical of their particular industries. This Tracking Study should be considered a longitudinal, virtual focus group, with all of the method's virtues and limitations. Informants were promised that their identities and those of the organizations they represent would remain confidential.

Discussion guides were developed for each wave of interviews. Guides were specific to each organizational component of the systems studied. The guides were prepared and circulated to informants for their use prior to and during discussions. Informants were asked not to fill out the discussion guides, but rather to review them and to keep them handy during their interviews in an effort to make the process more efficient and less time consuming and to ensure that they had necessary information at hand prior to interviews.

Reflecting the focus on decision makers in organizations that affect the adoption, reimbursement, and dissemination of buprenorphine treatment, one significant source of information not accessed was the private sector self-pay market among practitioners and patients who do not seek third party payment for buprenorphine treatment. The size of this market segment was not well known, but was inferred from evidence reported in the Patient Study conducted as a separate component of the Evaluation of the Buprenorphine Waiver Program. That survey found that 32% of patients reported using only personal, out-of-pocket funds to pay for the buprenorphine medication itself and 42% of patients reported using only personal funds to pay for physician visits.

3. PROCEDURES

The Tracking Study conducted interviews with 10 to 12 key informants in each of four waves, beginning in January 2004 with a report on informants' 2003 experience with buprenorphine. Subsequent Tracking Study reports were based on interviews in April 2004, covering the first quarter of 2004; November 2004, covering the second and third quarters of 2004; and May 2005, covering the fourth quarter of 2004 and the first quarter of 2005. All interviews were arranged and conducted by experienced interviewers over the telephone, with interviews typically lasting from 10 to 45 minutes. Informants voiced no concerns regarding the interview questions, interview length, the periodic repetition of interviews, the lack of reimbursement or the length of the study commitment, perhaps because agreement to participate had been secured initially at senior levels of management. Participants received the periodic Tracking Study reports as they were approved.

Discussions for the Tracking Study were held with informants from the following categories of organizations:

Organization Type	Number of Informants Per Wave
Direct Public Payer / Organized Care System	3
Managed Behavioral Health Organization (MBHO)	1 – 2
State Substance Abuse Agency	1 – 2
State Medicaid Agency	1
Pharmacy Association	2
Drug Distributor	0 – 1
Pharmacy Benefit Manager	1

In the 18 months of the Tracking Study, the composition of the respondent panel evolved to some extent. Some of the organizations and informants changed because of organizational and personnel changes typical of the large organizations in this study. As the table above notes, the numbers of respondents by organization type varied in the waves of discussions. Issues and concerns were very different for individuals from these different types of organizations, and no more than nine individuals were asked the same set of questions during the data collection process.

4. TOPICS COVERED IN TRACKING STUDY

The Tracking Study interviews highlighted the following topics, which are discussed in this order:

1. **Reported Activity Related to Buprenorphine.** All decision-related activity–meetings, conferences, recruitment efforts, approval or exception processes–related to buprenorphine during the period covered by the Tracking Study;

2. **Formulary Issues.** The formulary or preferred drug list status of buprenorphine and the reasons for decisions regarding placement of the medication on the formulary or preferred drug list;

3. **Benefit Design Issues.** The extent to which the design of substance abuse benefits in public and private programs appears to present payers, clients, and providers with obstacles or avenues to encouraging buprenorphine treatment dissemination;

4. **Price/Cost Issues.** The extent to which informed decision makers feel that the price or cost of buprenorphine as a medication and/or as an outpatient treatment appears to be affecting payer coverage and formulary decisions;

5. **Requests to Approve and Reimburse Buprenorphine.** The reported extent to which practitioners, clients, and/or health plan divisions are spontaneously asking health plans, organized care systems, or third party payers to approve and reimburse buprenorphine as a medication and as a treatment approach;

6. **Special Rules and Regulations.** The extent to which organized care systems and large purchasers or public agencies report that they already have particular medication and treatment approval processes that apply to buprenorphine and outpatient treatment with the medication or that they are enacting buprenorphine-specific rules and procedures affecting client access to treatment, prescribing, and availability;

7. **Consumer and Practitioner Interest in the Medication or Treatment.** The extent to which key informants feel that lack of interest in or lack of familiarity with buprenorphine treatment is or is not a problem in attracting requests from prescribing practitioners, pharmacies, or clients for the medication and the treatment;

8. **Distribution or Supply Problems.** The extent of any supply or distribution interruption problems that decision makers and payers mention as contributing to an early reluctance to order supplies of the medication or to health plan/care system practitioners' eagerness to offer the treatment;

9. **Practitioner Specialty Issues.** The extent to which health plans/care systems mention that certain types of practitioners, such as primary care physicians within their system or contracted networks, have voiced enthusiasm or reluctance about offering buprenorphine treatment or have shown knowledge of the treatment;

10. **Attempts to Negotiate Price.** The extent of successful or unsuccessful attempts to negotiate the price of the medication with the distributors or manufacturer of buprenorphine and the outcome and the impact of those attempts.

11. **Contact with Representatives of Manufacturer.** The extent to which there is any report of direct contact (initial or repeated) by the medication's manufacturer representatives with each component/informant from the buprenorphine distribution/reimbursement/retail pharmacy systems being interviewed for this study; and

12. **Other Issues.** Other significant issues mentioned by respondents surrounding the payment and distribution system for buprenorphine.

5. TRACKING STUDY INFORMANT RESPONSES

5.1 Reported Activity Related to Buprenorphine

During the period covered by the first Tracking Study, calendar year 2003, many organized care systems, distributors, PBMs and MBHOs began to consider buprenorphine for placement on a formulary. Public sector payers (state substance abuse agencies and Medicaid agencies) also reported considering the status of buprenorphine in their systems. Some drug distribution companies and pharmacies prepared for the introduction of buprenorphine. There was considerable preparatory activity during 2003, but, as the ARCOS data cited above demonstrate and Tracking Study findings corroborate, the actual distribution of buprenorphine had a slow start in 2003.

Both the drug-distribution and the PBM informants noted that the time required for completion of the FDA approval process for buprenorphine delayed their own routine processes for getting the medication into distribution and onto customers' formularies. All interviewed organizations involved in the distribution system, however, reported considerable activity during 2003 to prepare the systems and processes for distributing this medication. Organizations involved in the reimbursement and organized care systems reported beginning their process of consideration only in the late summer of 2003. Two informants commented that the lengthy FDA approval process had set their respective pharmacy and therapeutics (P&T) committees considerably behind in considering the medication. A state direct payer noted that the delayed debut of buprenorphine might still have been contributing to the state's physicians' not advocating its use, even though it was listed on the state's Medicaid preferred drug list. The public substance abuse treatment policy, planning, and education process began with passage of the DATA 2000 legislation, anticipating FDA approval. Some of the physician and state agency readiness and education effort by public sector stakeholders was based on expectations of the release of buprenorphine earlier than the actual October 2002 approval date, and may have been premature.

According to the second Tracking Study report, there was significant activity among the key actors participating in the study during the first quarter of 2004. Four informants reported new activity related to buprenorphine during the quarter. Two informants reported that their organizations were in the process of developing new policies, procedures and guidelines for use of buprenorphine. An informant from a public organized care system that had not placed buprenorphine on its formulary reported considerable activity on the local level related to buprenorphine. The informant from a pharmacy

association reported the association had held national meetings during which there was a panel discussion of buprenorphine as well as two educational sessions. The association was in the process of developing a one-and-a-half hour continuing education course on addiction. In addition a monograph on buprenorphine, supported by SAMHSA/CSAT funds and based on the panel discussion, was published in the May 2004 issue of the newsletter, which reached 117,000 members.

The third Tracking Study report, reflected experience in the fourth quarter of 2004 and the first quarter of 2005. It noted a considerable increase in buprenorphine-related activity among organizations involved in the reimbursement system compared to earlier time periods. Some informants (all from the pharmacy benefit management and pharmacy associations) reported no activity during this period because they had already successfully incorporated buprenorphine into their routine processes. In contrast, informants from five organizations in the reimbursement system reported considerable activity related to the medication. Numerous activities, discussions and emails about buprenorphine in the prior six months were reported by informants from three organized care systems/health maintenance organizations (HMOs), one from a managed behavioral health organization (MBHO), and one from a State Medicaid agency. One informant from an organized care system reported that a major substance abuse treatment initiative was under way. Another informant from a large MBHO reported development of new practice guidelines for treatment of opioid dependence and abuse. Finally, a State Medicaid agency reported that guidelines for use of buprenorphine in the Medicaid program had been completed but were awaiting final agreement from all parties.

The fourth Tracking Study report reflected experience in the fourth quarter of 2004 and the first quarter of 2005. Once again, there was an increase in activity, but +none of the informants from the three pharmacy benefit management and pharmacy associations reported any discussions or activity related to buprenorphine, although the pharmacy benefit manager did report an increase in the amount of buprenorphine shipped. One informant noted that the lack of discussion may have been attributable to the maturation of use of buprenorphine and the increasing familiarity of the processes and procedures related to buprenorphine employed by their organizations and customers. The medication was increasingly employed by practitioners experienced in its use, so the need for discussion and communication declined.

Respondents from an MBHO reported engaging in recruitment efforts to find physicians willing to accept referrals for treatment with buprenorphine at managed care payment rates. They found that many waivered physicians they approached did not want opioid dependent patients in their practices. Others believed that managed care payment rates were too low. Finally, in some regions of the country,

few employers asked health plans or PBM's to place buprenorphine on their formularies. As a result, informants who represent an MBHO with extensive market share in the U.S. concluded that extensive and personal outreach would be necessary to recruit network physicians willing to prescribe buprenorphine.

Throughout the Tracking Study interviews, informants frequently attributed increases in buprenorphine use to local physician "champions" who successfully advocated use of the medication in their area. Other respondents mentioned the need to have a respected and persistent buprenorphine "champion" within an organization to advocate coverage and formulary status.

5.2 Formulary Issues

5.2.1 Basic Background on Formularies

Nationwide, medication payers in the U.S. use either formularies or preferred drug lists of approved medications they want to make available to their covered enrollees. These lists of preferred medications often reflect decisions about which medications the payers want to put forward as best for prescriptions. Such a designation is typically used to identify medications that should be considered first by network providers, for clinical reasons, economic reasons, or a combination of the two.

It is important to understand that attaining formulary or preferred drug list status is necessary but not sufficient for a medication such as buprenorphine to be prescribed. It enables waivered physicians to prescribe the medication within the parameters of the third party payment systems, but the physicians must want to be prescribers and their patients must want the treatment and be covered for it or be willing and able to pay for it themselves.

Most public and private sector health plans and organized care systems have established P&T committees with standardized steps for considering the safety and efficacy of new medications and recommending whether or not they should be on that system's formulary. P&T committees typically meet quarterly and are similar to equivalent health plan committees that consider covering new procedures, including buprenorphine treatment, or durable medical equipment and devices. Factors considered in making decisions include demand for the new medication, indications for prescribing it, safety and efficacy, and cost effectiveness. The Blue Cross Blue Shield Association headquarters office in Chicago undertakes such reviews and has an entire department devoted to these considerations on behalf

of the their coverage plans. The VA has a similar mechanism for pharmaceuticals and another for new treatments, devices, and approaches.

A formulary can be either “open” or “closed,” meaning that it is either an open nonexclusive, non-mandatory list of preferred medications, or it is a closed/restricted formulary list of medications that are the only ones that will be covered without an exception. Exceptions to formulary medications are permitted through a multi-stage formal exceptions process that requires physicians to justify using the medication in order for the patient to be reimbursed for it by the care system or health plan. Formularies have been common in commercially insured populations since 1990 and are now common in public sector health plans and organized care systems as well. They are part of a group of administrative and financial mechanisms, such as preferred drug lists, required drug utilization management, and tiered copayments used to manage the use and costs of medications. Consumer economic demand controls such as copayments increase substantially as consumers move further away from preferred medications. Plans and purchasers use mechanisms such as formularies to try to steer providers and consumers towards what the plans consider clinically preferred, cost-effective medications and away from those considered ineffective or too expensive.

The five health plan/organized care systems informants agreed that gaining formulary status in their systems does not necessarily constitute an endorsement of a medication, nor lead to its prescription or use. It simply enables preapproved prescribing by those who are interested and have the required expertise and patient demand. According to the informants, other care system actions, activities, and vehicles for dissemination, such as publishing evidence-based protocols or guidelines, offering continuing medical education (CME) or counselor training, or issuing pharmacy “alerts” that explain the indications and appropriate use of the medication may be more important than a medication’s formulary status. Without an understanding and strategic approach to these processes, new medications and treatments may languish, as was the fate of naltrexone and LAAM.

Buprenorphine is considered a “niche” medication by plans because, in the form of Subutex® and Suboxone,® it is prescribed for a single indication, opioid dependence, which is thought to affect a limited number of covered individuals. However, there are few if any covered alternative medications to buprenorphine listed on the formularies. Although some commercial health plans and managed behavioral health companies with large public sector enrollments have approved and reimbursed individuals for methadone treatment, many plans do not pay for that medication or cover the visits connected to it. Medicaid, for example, has provided substance abuse treatment as a state option. Some

states reimburse Medicaid patients for methadone treatment and detoxification, but many do not. The same is true of buprenorphine, even when it is on the formulary.

5.2.2 Findings on Formulary Issues

The issue of formulary status was carefully considered in the Tracking Study, because formulary status is an important predisposing factor for prescribing buprenorphine and consideration for formulary status is the second step in the dissemination process. Informants reported that formulary consideration generally did not occur until late 2003 and that there was a divergence of decisions.

All five informants from organized care systems and MBHO's reported that it takes most plans about 6 months following formal FDA approval of a new medication for P&T and other committees to begin to consider a new medication. It may also take additional time to have a particular medication scheduled for consideration by the committee, depending upon the number of other medications that are also being considered, the amount of controversy or doubt about a particular medication, and how often the committee meets. For medications about which there is controversy regarding safety, efficacy, or cost-effectiveness, the time required can extend to a year or more, especially for a niche medication. Of course, the time required for consideration is also affected by how thoroughly and skillfully the proponents of a particular medication argue their cases, follow up on questions, and are able to satisfy any concerns of the committee members or the plan.

Since buprenorphine was not approved by the FDA until late October 2002, most health care/organized care systems could not have considered this medication until 6 months later – April or May 2003 at the earliest. In fact, the five informants who reported that their organizations considered buprenorphine indicated that dates of formulary consideration and approval or disapproval ranged from late summer 2003 to January 2004. They explained that the timing of the FDA approval and the time it took to consider the medication for formulary status meant that their systems could not have seen wide use of the medication during 2003 unless many consumers and practitioners had requested special consideration. Even then, requested exceptions would also have taken time to consider and effort, motivation, and time to request.

According to the pharmaceutical distribution informant, buprenorphine is regarded as a niche medication, not a "blockbuster" drug that can be used by a large patient population and generate

extremely large revenues. The distributor informant said the company was initially hesitant to purchase and arrange storage of Subutex® and Suboxone® but eventually did so after the manufacturer reportedly became more active in presenting it to the company and explaining its use and potential, beginning in the late second half of 2003. However, the distribution company informant reported that, while orders have been increasing, they are accumulating slowly and mentioned that the drug's nonformulary status in many systems might be leading to slow growth in its use during the early phase of its adoption.

PBM's are medication managers who work on behalf of public and private sector health plans, employers, and public and private payers. They make formulary recommendations for some customers, who almost always adopt them, but sometimes they simply administer formularies that large customers have developed themselves. The PBM informant interviewed for this study is from one of the largest PBM's in the U.S. and has over 1,200 organizations and systems as customers. As of January 2004 this PBM had not had any customers request buprenorphine be placed on its national formulary.

This informant reported that PBM's analyze new medications and perform utilization management duties for most of their customers and also negotiate prices and rebates for many of their large purchasers, including some health care and organized care systems and plans. The PBM informant for this study reported that buprenorphine was put on its formulary within six to eight months of FDA approval. No other substance abuse medications such as methadone and naltrexone are on its formulary at this time. Methadone treatment is also not typically a covered benefit for this PBM's customers, as the public clinics where methadone treatment is available are not in customers' managed care networks.

The five informants from organized care systems and MBHO's reported differing decisions on the formulary status of buprenorphine. Three informants, two public and one private, did not approve formulary status. Two put buprenorphine on their formularies but regarded it as a niche medication. However, neither of these had seen much uptake of the medication by the date of the first Tracking Study interview. In fact, one system reported that no prescriptions had been written for buprenorphine as of January 2004. That informant wondered why the organization had even considered the medication for formulary status.

The two informants from state substance abuse agencies reported divergent views. One acknowledged that private sector physicians were prescribing buprenorphine but said that public sector program prescribing required that the patient be enrolled in a state-certified substance abuse treatment program for the prescription to be approved by Medicaid. The other reported swiftly putting

buprenorphine on the approved drug list for Medicaid but said that there had been few requests for the drug as of January 2004.

The informant from the pharmacists' association said that member pharmacists had not shown much awareness of the medication or the formulary issues as yet, although the association had written a pharmacy "alert" on the topic, supported by CSAT funds.

To summarize the findings on formulary status from the first round of interviews, just three out of seven of the managed care / direct payers / State / organized system organizations reported that they had placed buprenorphine in their formulary and those that did so did not see many prescriptions written.

The second wave of Tracking Study interviews found continuing differences in decisions regarding formulary status of buprenorphine. Three informants, two from private organizations and one from a public sector organization, still had not included buprenorphine on their formulary as of April 2004. Informants from organized care systems mentioned the 30 patient limit and the cost of buprenorphine as the most important reasons why buprenorphine remained off the formulary. One private sector organization experienced a turnover in the pharmacy leadership. An informant with interest and knowledge of buprenorphine left the organization and was replaced by a new director of pharmacy who had no knowledge of buprenorphine or any information about the Waiver Program.

The third wave of the Tracking Study again revealed a mixed picture of the placement of buprenorphine on formulary lists. The informant from a group-staff model HMO reported that buprenorphine had been added to its formulary in the past two or three months. However, very few patients were treated with buprenorphine because of the legislative limit of 30 patients in treatment within the entire organization.

The fourth wave of Tracking Study interviews again revealed a mixed picture regarding the placement of buprenorphine on formulary lists. Informants from an MBHO mentioned that although they had placed buprenorphine on their formulary, there remained an important issue with the formulary status of buprenorphine for health plans of many employers. In some regions, few employers had buprenorphine on their formulary and informants reported instances of resistance by employers and health plans based on fear of adverse selection when hiring employees and unwillingness to consider addiction treatment as a legitimate expense for employers to bear. However, another informant from a payer system mentioned

that in that organization formulary status was not a significant issue because of a widely used exception process with few denials. Therefore, the issue is not the formulary status alone but also the ease or difficulty of obtaining exceptions when a medication is not on the formulary or preferred drug list.

By the time of the fourth Tracking Study interviews, five out of six of the managed care / direct payers / state / organized system organizations reported that they had placed buprenorphine on their formularies. Of course, the composition of the panel changed over time so a direct comparison with the results from the first study is not precisely appropriate; nevertheless, over the course of the Tracking Study informants were increasingly likely to report the inclusion of buprenorphine in formularies.

5.3 Benefit Design Issues

In the health care system of the United States, management of pharmacy benefits is often separate from management of benefits for treatment, including substance abuse. Substance abuse benefits are also handled separately from other medical benefits. All informants were asked what affect the design of health plan benefits appeared to be having on the availability of buprenorphine. Benefit design issues changed little during the course of the Tracking Study.

Concern about providing benefits for substance abuse treatment as an obstacle to coverage of buprenorphine was an ongoing theme of the Tracking Study. A medical director of a large MBHO reported that certain treatment benefits were available, but the medication itself was not on the formulary of its parent health plan. The physician director said that while the benefits were theoretically available for some of its customers, depending on their plan designs, the plan itself was "concerned that providing these benefits or information about buprenorphine could lead to undesirable adverse selection affecting the health plan's bottom line." This managed behavioral health plan had "not actively tackled substance abuse benefits" and was resistant to doing so. Its clientele consists primarily of commercial employers and, in the medical director's opinion, their concerns about the attraction of opioid addicted persons to employers with comprehensive substance abuse treatment coverage could have discouraged them from offering such coverage. The informant did acknowledge that many employers currently have employees with substance abuse problems that, if treated, would improve productivity.

Other informants did not report such concerns or perhaps did not want to acknowledge them. In fact, an informant from a private, not-for-profit organized care system said that substance abuse

benefits were a standard part of coverage, administered by a contracted managed behavioral health organization. An informant from a managed behavioral health organization said that all components of substance abuse outpatient treatment were covered by some customers but that medications such as buprenorphine might not be a covered benefit for others. In general, medication is not directly under the control of an MBHO because the organization does not provide medications or even manage formularies, although an associated sister company may do so. An MBHO interacts with its customers directly about medications for treatment of substance abuse only when it is asked by customers to participate as a consultant in pharmacy or health plan new treatment committee meetings.

As in the private sector, informants reported divergent benefit design and coverage practices in the public sector. In states where buprenorphine treatment is covered, it may be restricted in a number of ways. One state substance abuse agency director said that participation in state-certified outpatient drug therapy was a requirement for the medication to be prescribed to public sector clients and covered by Medicaid. Medication coverage is a part of this state's Medicaid benefit, and buprenorphine was on the state's approved drug list, but the informant pointed out that outpatient substance abuse treatment benefits were optional under Medicaid and that neighboring states had begun to drop those optional benefits. The informant also indicated that substance abuse treatment of any kind was not an entitlement under Medicaid.

A state Medicaid official responded that, while buprenorphine was added to the state list, treatments covered were primarily for outpatient substance abuse services, most of which were available only in the state's mental health centers. If someone needed buprenorphine but was not near one of the mental health centers, the treatment could not be covered by the public sector. However, the informant felt that buprenorphine would eventually be helpful in extending outpatient substance abuse treatment for opioid dependence in rural areas of the state, especially to areas where there were few or no methadone clinics or mental health centers. Medication visits from physicians in this state were covered for public sector clients only if the person was included in one of the state's target populations. Substance abuse benefits were not limited to outpatient services but there were distinct coverage limits. What a particular patient received in the public sector depended on his or her Medicaid eligibility, not on the benefits themselves. Some of the Medicaid benefits that pertain to substance abuse treatment (the medication benefits) were subject to patient copayments and the size of these copayments was likely to grow.

A respondent from a large public organized care system in which many patients were receiving substance abuse treatment reported that benefits for buprenorphine treatment were available, but

also that the clinical guidelines currently in use required that the treatment be provided only when a client has a medical reason for not being able to use methadone or lived in a region where a methadone clinic was not available.

To summarize, although many Tracking Study informants did not report or acknowledge concerns about missing or inadequate substance abuse coverage, they reported that limitations to the coverage of treatment of substance abuse with buprenorphine reduced its use. Moreover, informants reported that some organizations and employers opposed coverage of substance abuse treatment with buprenorphine due to fears of adverse selection and / or unwillingness to consider addiction treatment as a legitimate expense for employers to bear.

5.4 Price/Cost Issues

All respondents were asked to address the issue of costs and pricing. The cost of the medication continued to be a key issue for organizations in the payment and reimbursement system throughout the period covered by the Tracking Study. It was not an issue for drug distributors or retail pharmacists, except to the extent that the price negatively affected the quantity of buprenorphine demanded. An informant from a drug distributor reported that price was not an issue because buprenorphine was a niche drug for a special indication. The PBM informant agreed with this characterization.

However, most respondents from organizations involved in the payment and reimbursement systems indicated that the cost of buprenorphine was either somewhat of a concern or a major concern. In the first wave of the Tracking Study, an informant from a state substance abuse agency said that "buprenorphine and similar drugs are not a panacea for addiction and unless we find a real panacea drug for addiction, you won't find buprenorphine or other medications used widely due to costs." An MBHO informant said that the corporate parent health plan had rejected his request that buprenorphine be put on its formulary because of concerns about increased costs for treatment, as well as pharmacy costs. Two state purchasers indicated that the cost of the medication relative to methadone was an obstacle in the public sector, especially in light of state and Federal budget deficits.

Substance abuse treatment costs, rather than medication costs, were the concern of one managed behavioral health plan informant. This informant said that a few of its customers were interested

in providing case management for buprenorphine treatment but that many were very concerned about limiting increases in overall behavioral health treatment costs, including those for substance abuse.

An informant from an organized care system reported that costs of lab tests, therapy, and visits were not an issue and that the system had not asked its contracted PBM to negotiate the price of the medication. The informant felt there would be “no point in doing so” for the medication because it was the only product in its niche. However, these costs were not an issue since all costs over $1,500 a year for medications and therapies were scrutinized and treated as individual exceptions requiring case-by-case approval.

Another organized care system respondent indicated that its national pharmacy committee conducted an assessment and found that the cost-effectiveness of buprenorphine was questionable compared to methadone. This informant also pointed out that budget cuts in the capitated organized care system, and the same or an increase in the number of patients had resulted in some primary care physicians being hesitant to provide the treatment, especially if buprenorphine patients were to be seen in primary care. The price of the medication was initially an issue but the costs of care became an issue as well, due to funding cuts and an influx of new patients.

Informants from organized care systems that had not placed buprenorphine on their formulary identified the cost of the medication as one of the critical factors preventing further consideration. They specifically noted an unfavorable comparison of the cost of buprenorphine to the cost of methadone. Respondents from a state Medicaid program reported that many public mental health and substance abuse treatment providers found that the cost of the medication prevented them from using it for publicly funded patients. Informants from a state substance abuse agency reported that “maintenance” treatment with buprenorphine was limited to six months, in part due to cost considerations. A respondent from a large public payer reported that the cost of the medication had not prevented adoption of buprenorphine, but had delayed implementation of the treatment.

5.5 Requests to Approve and Reimburse Buprenorphine

Throughout the course of the Tracking Study, informants all noted that they had received few requests for buprenorphine. In the first wave of interviews, a drug distribution company that acquires pharmaceuticals for nearly 30,000 pharmacies and hospitals stated, “none of our clients has yet requested

that buprenorphine be added to the list of drugs we distribute; we added it ourselves in April 2003." The PBM informant said that buprenorphine was not currently important to her customers because they were preoccupied with other issues. No customer among 1,200 health plans and large employers had requested action regarding buprenorphine, and no claims had been filed since the medication went on the national formulary in the second half of 2003. The PBM had not been asked by any customer to review or make recommendations for buprenorphine medication treatment guidelines.

A state direct payer indicated that there was some use of buprenorphine in the private sector but very little interest in the public sector. Another state payer said that although there are problems in the state with insufficient access to substance abuse treatment, there was minimal demand for the medication, except for one clinical trials site. This informant said that only state-employed physicians, researchers, or "notorious" physicians (who the state thinks write prescriptions too freely) were asking for and prescribing buprenorphine.

A health plan respondent said that it received a few calls at its managed behavioral health care subsidiary about benefits available to clients for whom they are prescribing buprenorphine but "not enough to generate any activity." No customers requested that buprenorphine be added to the health plan formulary. Two staff members had attended training sessions to receive a waiver, but no network providers reported doing so.

Another health plan payer reported that it had received no requests through its case management interactions with providers. Similarly, there were no requests from covered enrollees, employers, or network physicians. An organized care system reported that although buprenorphine was on the formulary, no enrollees or practitioners had requested approval for the treatment or the medication as of January 2004. When this payer put the medication on its formulary, no one on its P&T committee had ever heard of the medication. Another organized care system said there had been a lack of awareness and interest in buprenorphine treatment from its regions and physicians. That lack of interest figured in its decision to monitor off-formulary requests for the treatment/medication until demand warranted reconsideration. A state direct payer said only one call about a request for buprenorphine coverage had come in as of January 2004 and it was from the state's Department of Mental Health, not from a Medicaid enrollee or a practitioner.

Although the second wave of the Tracking study received similar responses to this item, two informants, one from a large public organized care system and one from a private MBHO, reported a

number of requests for buprenorphine from enrollees and providers during the first quarter of 2004. In both cases, individuals in leadership positions had an interest in buprenorphine and expressed their interest to others further down the organizational hierarchy. In both cases clinical materials and guidelines related to buprenorphine had been actively distributed throughout the organization.

The third wave of the Tracking Study noted that a buprenorphine "champion" at one organization was working to approve coverage for buprenorphine in their health plans and formularies. The P&T committees at individual health plans were sent a letter advocating inclusion of buprenorphine for both detoxification and maintenance in their formularies. Interestingly, these activities occurred in the absence of customer requests. The fourth wave of interviews documented a continuing lack of requests for buprenorphine and once again observed that demand for the medication came from "champions" of the medication who were located in organizations that are part of this system and from informal communications among patients and physicians, rather than from requests for reimbursement from patients, physicians and employers.

5.6 Special Rules and Regulations

The first interviews in the Tracking Study identified a variety of special rules and regulations that were applied to buprenorphine. These continued to evolve over the course of the study. At first payers and organized care systems reported various approaches to having or not having rules and regulations specifically for buprenorphine.

- A state direct payer said there were specific utilization management rules for approving buprenorphine. The state had its own buprenorphine clinical guidelines, drawn from national and in-house literature reviews, Revia® (naltrexone) protocols, and approved procedures for treatment, to which the medication is considered an adjunct.

- A health plan representative said that the medication was not covered at all. The medication/treatment was considered via utilization management only, with no buprenorphine-specific guidelines. Buprenorphine was not on the plan's formulary because it was not considered significant. The P&T committee of the plan lacked a medical director to lead the formulary process at the time.

- Another state direct payer said that no special rules were imposed for buprenorphine but that the only public sector patients eligible to receive it were in its designated target block grant populations those eligible for Medicaid.

- A managed behavioral health informant said that it had no utilization management guidelines for buprenorphine as a medication but that there were guidelines applicable to all substance abuse treatments, both inpatient and outpatient.

- Another health plan said that there were utilization management processes which were handled by its PBM for the medication, but the treatment had to be authorized by its managed behavioral healthcare vendor. The vendor had substance abuse guidelines but they were not specific to buprenorphine.

- A direct payer/organized care system said that there were nonformulary status guidelines, clinical guidelines specific to buprenorphine, and requirements for the characteristics both of the physicians who prescribe and the patients who take buprenorphine. Physicians had to be waivered and be treating medically and psychologically stable patients already in maintenance, with a job or in school. The medication was not on the national formulary and so could be prescribed only through an off-formulary exception process initiated by the prescribing physician.

- A final direct state payer said that medical necessity determination would apply for Medicaid to approve the treatment. However, the pharmacy staff recommended the medication with no specific rules or regulations other than what the state's treatment centers (typically mental health centers) normally impose on treatment.

Informants from the pharmacy sector indicated that concern about Drug Enforcement Agency (DEA) involvement and regulations was slowing broader adoption and dissemination of buprenorphine. A pharmacy association informant said that it was preparing a newsletter on narcotic addiction and treatment and would be sending this out to all members in April 2004. A discussion of buprenorphine was included. However, this informant said that its members were "very confused regarding the governmental regulations specific to buprenorphine and not eager to deal with the DEA verification and audit procedures for the medication." Another informant felt that the cost of adhering to government regulations was a major reason why more pharmacies were not stocking buprenorphine. The respondent explained that the attendant DEA verification and audit procedures were regarded as "burdensome, confusing, and expensive" and felt that the regulations were a bigger concern for members than the cost of the medication itself. This informant said that the recordkeeping issues with buprenorphine were significant to pharmacies.

Drug distributors did not report having any special rules and regulations for buprenorphine and indicated that "buprenorphine is a niche product, one of many, and is perceived as a routine pharmaceutical product that is distributed along with others." Similarly, the PBM informant was not aware of any special guidelines or approval processes specific to buprenorphine among the 1,200 customers it serves.

In the second wave of interviews, two informants reported engaging in processes to modify procedures for use of buprenorphine. An informant from a state Medicaid agency reported that they were in the process of developing new guidelines for treatment with buprenorphine. The informant expected that the guideline development process would be completed and the guidelines posted on the agency's website by the end of the year. However, an ongoing mental health and substance abuse system-wide reform process in that state essentially overwhelmed other efforts, including the effort to introduce treatment with buprenorphine.

An informant from an MBHO reported that the medical leadership of the organization was engaged in the process of developing a "soft medical policy" with medical necessity criteria related to buprenorphine. These medical necessity criteria were to reinforce existing policies on the treatment of substance abuse and identify those patients appropriate for treatment with buprenorphine. The policy was "soft" because it did not *require* such treatment. . This informant believed that this would be an important step for this organization in the institutionalization of substance abuse treatment using buprenorphine.

The third wave of Tracking Study interviews followed continuing guideline development at a large MBHO; by the time of the fourth wave, all reported modifications to special rules and regulations regarding buprenorphine had been completed.

5.7 Interest in the Medication or Treatment

In the first wave of Tracking Study interviews, all 12 respondents observed that even though some of them had written guidelines for the treatment and had put the medication on formularies or stocked it for distribution, there were very few requests for the medication from consumers, practitioners, or employers. Respondents had various theories about the reasons for this, ranging from lack of knowledge of the medication or the treatment, to fear of drawing addicted persons into the health plan or pharmacy and reluctance to deal with the required recordkeeping and potential DEA audits. However, by the time of the second and third waves of interviews, there were indications of increasing interest in buprenorphine treatment, but these varied by organization. Informants from organized care systems that participated in the fourth wave of interviews, however, reported that patient demand warranted recruiting additional network physicians into their organization to provide treatment with buprenorphine, although they experienced difficulty in doing so. Informants reported that many of the physicians they approached were reluctant to accept patients into their practice for treatment of their substance abuse problems.

By the time of the fourth wave of interviews, several informants from managed care organizations reported that extended detoxification with buprenorphine on an outpatient basis provided them with an extremely effective opportunity to engage patients in ongoing treatment. Buprenorphine detoxification could lead to continued participation in a treatment program. One informant contrasted this process to his organization's experience with inpatient detoxification. The latter was medically effective but was never followed by having patients return for additional treatment.

5.8 Distribution or Supply Problems

At the time of the first interviews, Suboxone® and Subutex® had been approved by the FDA for treatment of substance abuse for a little over a year. Although there had been some initial anecdotal reports of supply problems immediately following FDA approval, by January 2004 no informants reported any significant supply or distribution problems. One of the pharmacy association informants said that there were probably still secondary supply problems because pharmacies were not ordering the medication unless a physician who specialized in the treatment came to them with a request. Both pharmacy association informants reported that pharmacists were somewhat reluctant to stock buprenorphine, so that patients who wanted to purchase the medication might well have problems finding a pharmacy that stocked it. No actual distribution or supply problems were reported in subsequent waves of the Tracking Study.

5.9 Practitioner Specialty Issues

One theme that emerged throughout the Tracking Study was that primary care physicians were reluctant to offer buprenorphine treatment and organized care systems were reluctant to encourage them to do so. Informants from organized care systems generally reported that they were most comfortable approving use of buprenorphine by addiction medicine specialists for treatment of a carefully defined set of conditions and patients. Even in organizations with less restrictive policies, informants reported that the majority of patients treated with buprenorphine were treated by programs specializing in addiction treatment. It was rare for a patient to go to a non-addiction specialist for substance abuse treatment.

The only respondents who mentioned that certain types of practitioners were eager to provide the treatment were one direct state payer who said “the true believers” and medication-only private sector physicians were eager to offer the treatment and another direct payer who said that unfortunately many of the “notorious prescribers” in the state were eager to provide the treatment and the medication and that the state was watching them closely.

5.10 Attempts to Negotiate Price

The Tracking Study asked informants if they had attempted to negotiate the price of buprenorphine with the manufacturer or distributor. Informants reported that the ability of a purchaser to negotiate a discount for a given medication depends largely on the existence of competing medications for the same indication. It is the purchaser’s ability to significantly influence the choice of medication in such a situation that provides a basis for price negotiations with a manufacturer. The incentive to undertake price negotiations over a single drug also varies directly with the sales volume of that drug. Since there were no medications comparable to buprenorphine on most formularies, and since buprenorphine was not expected to sell at high volumes, there was little opportunity to negotiate over price.

5.11 Contact with Representatives of Manufacturer

Throughout the course of the Tracking Study, few informants reported contact with the manufacturer, Reckitt Benckiser, but reports of contacts did increase somewhat over time, particularly among informants from organized care systems. Reckitt Benckiser hired managed care representatives in 2005.

5.12 Other Issues

Discussions with informants during the course of the Tracking Study illuminated several unanticipated issues surrounding the payment and distribution system for buprenorphine. An informant from an IPA model HMO reported that treatment using buprenorphine in an environment in which physicians are paid by capitation presented some challenges for the health plan. For example, when an

existing patient of a primary care physician (PCP) needs to receive buprenorphine treatment from another physician, also paid by capitation, how is the capitation handled? Similarly, how is the capitation to be handled when one physician starts the treatment with buprenorphine and then transfers the patient to another physician for ongoing maintenance? The plan was still determining how these issues should be resolved in 2004.

An informant from a large MBHO reported that one of their very large health plan customers--one of the nation's largest health insurers--was in the process of approving buprenorphine for detoxification treatment only. They reported that this large health insurer feared coverage for maintenance would “open the floodgates.” Another informant from another MBHO reported no plans to add coverage for buprenorphine in places where it was not covered, as a result of concerns about adverse selection; it was covered only where mandated by State legislation or as a result of the acquisition of a plan that already covered buprenorphine.

Another informant reported that that many treatment organizations would only perform detoxification with buprenorphine on an inpatient basis until their practitioners developed the skills and confidence to do it on an outpatient basis. This was primarily a training issue and reflected many inexperienced practitioners’ lack of confidence about the course of detoxification.

6. SUMMARY OF KEY FINDINGS

- Distribution of buprenorphine got off to a slow start in 2003. There was considerable preparatory activity during 2003, but shipments of the medication did not increase rapidly until 2004. All organizations involved in the distribution system, however, reported considerable activity during 2003 to prepare the systems and processes for distributing this medication. A six to nine month lapse between the October 2002 FDA approval of buprenorphine and health plans' and payers' consideration for formulary status meant most organizations in the Tracking Study did not consider buprenorphine for formulary status until late summer of 2003.

- Respondents reported that, although some of them had written guidelines about the treatment and had put the medication on formularies, there had been little expression of interest in and few requests for the medication or the treatment as of January 2004. This was an ongoing theme throughout the Tracking Study. Respondents had varying theories about this, ranging from lack of knowledge of the medication or the treatment, to reluctance to draw addicted persons into health plans and pharmacies, and reluctance to deal with the required recordkeeping and potential DEA audits. Those informants who did report significant levels of interest in buprenorphine from patients and practitioners tended to be from organizations that actively facilitated or promoted use of buprenorphine.

- Non-formulary status in many systems in 2003 contributed to slow growth in use of buprenorphine during the early phase of its adoption.

- By the time of the last wave of Tracking Study interviews, five out of six of the managed care / direct payers / State / organized system organizations reported that they had placed buprenorphine on their formularies. The composition of the panel changed over time so a direct comparison with the results from the first study is not appropriate; nevertheless, informants were increasingly likely to report the inclusion of buprenorphine in formularies over the period covered by the Tracking Study.

- Concern about providing benefits for substance abuse treatment presented an obstacle to coverage of buprenorphine.

- Concern about adverse selection deterred one large health plan from placing buprenorphine on formulary; there was also a report from a large MBHO that in some regions of the country few employers had placed buprenorphine on their formulary. The MBHO informant reported that there was often significant resistance from employers to inclusion of buprenorphine on their formulary based on fear of adverse selection when hiring employees or unwillingness to consider addiction treatment as a legitimate expense for employers to bear.

- Respondents from organizations involved in the payment and reimbursement systems indicated that cost was a major concern. Respondents from organized care systems that had not placed buprenorphine on their formulary identified the cost of the medication as one of the critical factors that was preventing further consideration. An

unfavorable comparison of the cost of buprenorphine to the cost of methadone was specifically noted. A respondent from a large public payer reported that the cost of the medication had not prevented adoption of buprenorphine but had delayed implementation of the drug.

- Price discounts for buprenorphine were not reported by any private organizations and remained unlikely due to the lack of close competitors on formularies in its therapeutic class and low sales expectations.

- A variety of special rules, approval processes, and regulations applied to buprenorphine and continued to evolve.

- Several informants mentioned the length of time required for practitioners to gain experience and confidence in the use of buprenorphine. Physician lack of experience and confidence led to reluctance to prescribe and/or insistence on extensive clinical support.

- The thirty patient limit appeared to be reducing the access to buprenorphine for some patients. Although this limit on group practices and staff model HMOs has been lifted, the continued application to individual physician practices remained an issue for physicians who specialize in buprenorphine treatment.

- Concerns among Tracking Study respondents about the availability of practitioners willing to prescribe grew.

- Several informants from managed care organizations reported that extended detoxification with buprenorphine on an outpatient basis has provided them with an extremely effective opportunity to engage patients in ongoing treatment.

- PCPs were reluctant to offer buprenorphine treatment and organized care systems were reluctant to encourage them to do so. Informants from organized care systems generally reported that they were most comfortable approving use of buprenorphine in their organizations by addiction medicine specialists treating patients with a carefully defined set of conditions. The majority of patients treated with buprenorphine under the auspices of organizations involved in the Tracking Study were treated by programs that specialize in addiction treatment.

7. CONCLUSION

Reports from informants representing large organizations throughout the payment and distribution system indicated that the adoption of buprenorphine proceeded in three phases:

1. Phase one consisted of development and implementation of processes and procedures for routine management of the new medication. This phase included the determination of whether or not to place the medication on a formulary and in which category it would be placed.
2. Phase two was a monitoring period. After implementation, organizations generally observed how policies and procedures functioned. During this period, informants reported little activity related to buprenorphine. There may be ongoing updates and education within the organization to remind stakeholders of the existing policies and procedures. The length of this phase varies, both by type of organization and, within type by when or if a "buprenorphine champion" emerges. In general, this is the final phase for organizations involved in the distribution system.
3. Phase three was characterized by the emergence of "buprenorphine champions" within some organizations involved in the reimbursement system; these were individuals who believed that increased use of buprenorphine would advance the objectives of their organizations. These individuals emerged from a variety of levels within an organization, but they did not emerge in every organization.

This phased process of dissemination occurred because the introduction of buprenorphine was really the introduction of a new form of addiction treatment: office-based, medication assisted treatment of opioid dependence. Organizations initially considered buprenorphine to be a new medication only. When evidence emerged that adoption of buprenorphine was proceeding more slowly than expected, buprenorphine "champions" emerged in many organizations to promote the use of this new addiction treatment and to urge the alterations in organizational procedures to accommodate its use. It was this phenomenon of routine introduction of the medication, followed by recognition of the need for changes in procedures demanded by a new clinical approach that led to the phased process of dissemination observed in the Tracking Study.

Evidence gathered by the Patient Study as well as this Tracking Study indicated that a significant portion of the initial dissemination of buprenorphine occurred outside the framework of organized systems of care, the public sector, and third party reimbursement in general. That is, a market for buprenorphine developed among practitioners and patients who did not seek third party payment for buprenorphine. However, this study also indicated that acceptance of buprenorphine in organized care systems, the public sector, and third party reimbursement in general was proceeding but remained incomplete. In particular, some employers and payers were concerned that coverage of any substance abuse medication could lead to adverse selection. Moreover, some were unwilling to consider addiction treatment as a legitimate expense for employers to bear. Nevertheless, use of buprenorphine is growing, both under third-party payment and self-pay arrangements.

The use of buprenorphine increased substantially over the course of the Tracking Study, spurred by ongoing efforts among the organizations participating to encourage physicians to integrate the medication into their clinical practices. This growth appears likely to continue, although moderating factors including the 30 patient limit on individual physician practices, the length of time required for physicians to become comfortable with prescribing the medication, and the reluctance of some payers to cover the expenses of substance abuse treatment will continue to have a negative impact on the rate of adoption of the office-based treatment of opioid abuse and dependence with buprenorphine.