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**Report to HRSA:
Opportunities to
Advance Clinical
Pharmacy Services
in Safety-Net
Settings**

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EXECUTIVE SUMMARY

This report to HRSA was requested to recommend how to generate improvements in the use of clinical pharmacy services across all HRSA programs in which medication plays an integral role in patient care. HRSA commissioned the report to support its response to the request made by the Senate Committee on Appropriations for a report on this topic (Report 109 287, July 26, 2006). The Committee's request was prompted by findings of the Mathematica evaluation of the HRSA clinical pharmacy demonstration projects that these services proved valuable to patients, health centers, and colleges and schools of pharmacy that participated in the study.

RATIONALE FOR THE REPORT

Improving medication safety is an urgent task. The Institute of Medicine reports that 1.5 million people are injured each year as a result of medication errors, resulting in billions of dollars in avoidable cost (IOM 2006). One estimate found that for every dollar spent on ambulatory care medications, another is spent to treat new health problems caused by the medications (Alliance for Aging 1998, Johnson and Bootman 1995). Further, medication therapy is a critical part of treating chronic conditions whose associated costs and human burden continue to grow, including diabetes, dyslipidemia, hypertension, and asthma. Safety-net providers that participate in HRSA programs serve populations that tend to have a higher prevalence of these diseases compared with other populations of similar age and gender, making medication safety and effectiveness at least as salient for them as for other providers.

Clinical pharmacists (PharmDs or Registered Pharmacists with additional training) have the knowledge and skill base to contribute to improved medication safety and effectiveness in ambulatory care settings, as well as hospitals. These individuals are trained to identify and resolve medication problems, including problems that originate within the health care system, such as prescribing errors, and problems that develop from patient behavior, such as a patient not taking a medication due to its cost or an adverse effect. Further, studies show clinical pharmacy services can add value by improving clinical outcomes for a range of chronic conditions. Studies of their effects on costs are more limited, but to date suggest in many situations they are cost-neutral, and may reduce costs in some situations (see Appendix A). For purposes of this report, clinical pharmacy services are services provided by a clinical

pharmacist that go beyond the dispensing of drugs and serve the purpose of promoting safe, effective care, through collaborative participation in patient-specific medication and disease management.

Despite their value, clinical pharmacy services are relatively rare today among safety-net providers. Therefore, the objective of the research conducted for this report was to use input from a wide swath of relevant organizations, literature, and data to develop options for advancing clinical pharmacy services among safety-net providers. This report first discusses the barriers to greater expansion of these services among safety-net providers, and then provides options for overcoming them. The options include actions the federal government can take, as well as opportunities for others, including state Medicaid agencies, professional and provider associations, and foundations.

BACKGROUND RESEARCH

Extensive background research was conducted by Mathematica Policy Research and the University of Minnesota for this report. Case study interviews were conducted with Federally Qualified Health Centers (FQHCs), disproportionate share hospitals (DSHs), and AIDS Drug Assistance Program (ADAP) sites that currently provide clinical pharmacy services in ambulatory care settings, to find out why they initiated the services, how they sustain them, and what outcomes they have achieved. A meeting of national stakeholders was held, convening representatives from 20 knowledgeable and interested organizations including safety-net provider organizations such as the National Association of Community Health Centers, pharmaceutical organizations such as the National Association of Chain Drug Stores, professional associations such as the American Pharmacists Association and the American Society of Health-Systems Pharmacists, academic representatives from the American Association of Colleges of Pharmacy, and other members of the 340B coalition. Two pharmacy consultants who specialize in safety-net provider pharmacy issues (Todd Sorensen and Zandra Glenn) contributed their field knowledge to the effort. Discussions were also held with nine colleges of pharmacy, and interviews were conducted with several state Medicaid agencies that do and do not currently pay for clinical pharmacy services.

SUMMARY OF FINDINGS

Safety-net providers that offer clinical pharmacy services embrace the struggle to maintain them because they find high value for patients and physicians; sometimes in hospitals, the services may help their “bottom line.” Discussions with safety-net providers who currently offer clinical pharmacy services find these organizations highly value sustaining these services, for the benefit of their patients and physicians; some of the DSH hospitals also reported the services are cost-saving. Since third-party payment for clinical pharmacy services is severely constrained, these organizations actively piece together financial support to supplement available Medicaid and Medicare payments. Supplementary sources include the general revenues of the organization, grants (particularly Ryan White grants, for ADAP sites), and staffing and/or funding from a local college of pharmacy.

For the most part, safety-net providers do not have much financial incentive to provide clinical pharmacy services, and as such, their incentives are not well-aligned with the interests of the health care system as a whole. Primary care-focused safety-net providers such as FQHCs will not benefit from reduced hospitalizations and emergency department (ED) visits by their patients, although hospitalizations and ED visits are major drivers of cost for the health care system overall. DSH hospitals may capture some savings from reduced inpatient and emergency costs for their indigent patients, however, among insured patients, Medicaid, Medicare, and private insurers will capture any savings generated by clinical pharmacy services to their patients, while the hospital experiences reduced inpatient and ED revenue to the extent utilization is reduced for insured patients.

The benefits recognized by safety-net providers that have implemented clinical pharmacy services have not been effectively disseminated to the administrators and medical providers in other safety-net organizations. For example, several staff members of colleges of pharmacy interviewed to prepare this report cited safety-net provider administrators' lack of awareness of the potential benefits as a barrier to further expansion of the relationships between schools of pharmacy and these organizations.

The limited ability of safety-net providers to bill for clinical pharmacy services is the largest barrier to their expansion. Indigent patients and Medicaid patients comprise the lion's share of the patient population for safety-net providers. Only eight state Medicaid programs pay for clinical pharmacy services in any form.¹ Further, the programs in these states to date have reached only a small portion of the highest-cost Medicaid patients, rather than a broader segment with chronic conditions who might benefit from these services. While the medication therapy management benefit under Medicare Part D has been important in bringing the concept of clinical pharmacy services into the mainstream, its stringent eligibility requirements combined with low Medicare patient populations in primary care-focused safety-net settings mean it has provided little additional support for clinical pharmacy services in those settings.

Medicaid agencies and other payers may be less interested in expanding billing opportunities and lower eligibility requirements for these services than they would be if better cost-benefits information were documented and disseminated. Two relatively strong studies focusing heavily on low-income populations—one in a Medicaid program—have reported overall health care cost reductions. Other studies have reported significant reductions in emergency room visits and/or hospitalizations relative to a control group, a positive sign for cost reduction. In terms of reports from the field, Harris County Hospital District, a large safety-net provider, reports it achieved \$1.5 million in cost savings in 2005 alone from its diabetes-focused clinical pharmacy services. Nevertheless, more research needs to be done to fully understand the cost implications of clinical pharmacy services.

¹ These states are Minnesota, Missouri, Iowa, Florida, North Carolina, Wisconsin, Mississippi, and Utah (see Appendix E for program descriptions).

Rural safety-net providers face greater challenges than urban safety-net providers. First, the difficulty of recruiting and retaining pharmacists interested in working in safety-net settings is a challenge to widespread expansion of clinical pharmacy services in general, but even more so in rural areas, where 12 percent of the pharmacists serve 25 percent of the country's population (Epstein 1996). Second, some remote rural areas have populations too small to support addition of local clinical pharmacy services. While a few examples of clinical pharmacy services delivered via technology—"telepharmacy"—exist, they are relatively rare, probably at least in part because of the inability to bill for telephonically delivered clinical pharmacy services. Third, many rural health providers currently deliver pharmacy services through contract arrangements with local pharmacists/pharmacies rather than directly employing a pharmacist and having them work as a core component of the organization's team of providers. Yet local rural pharmacies are under financial stress (many have closed recently due to financial losses), making it less likely for rural health organizations to be able to engage local pharmacists in new activities unlikely to bring clear financial gain. Finally, rural health providers may be even less aware than other safety-net providers of the potential benefits of clinical pharmacy services. Rural health research on clinical pharmacy services has primarily focused on the inpatient setting. In addition, colleges of pharmacy interviewed to prepare this report were unfamiliar with critical access hospitals and rural health clinics and the opportunities they might offer for partnerships to help meet the needs of both rural residents and the schools.

OPTIONS AND OPPORTUNITIES FOR THE FEDERAL GOVERNMENT

Fostering the expansion of clinical pharmacy services requires addressing at least some of the issues described above. The federal government has some important levers with which to address barriers. For completeness, this report includes actions HRSA may take as well as actions for other federal entities. However, federal action alone will not result in widespread implementation of clinical pharmacy services among safety-net providers. State Medicaid agencies, foundations, and professional and provider associations are other key actors.

To address the need for better dissemination of the benefits of clinical pharmacy services from those who have them to those who do not:

1. **Establish peer-to-peer networking and educational efforts, including support for providers to use a clinical pharmacy financial planning tool.** Some FQHCs (including many ADAP sites) could implement clinical pharmacy services, if the benefits found in safety-net sites with these services were better known and supportive technical assistance was provided to plan for the services. The Pharmacy Services Support Center (PSSC), an existing HRSA-funded center to support comprehensive pharmacy services among HRSA-funded providers, is well-positioned to provide this support. The support can include assisting safety-net providers in using a new clinical pharmacy financial planning tool developed by Mathematica Policy Research and the University of Minnesota with funding from HRSA in 2007.

To lay the groundwork to address financial barriers:

- 2. Prioritize research to identify and then disseminate stronger evidence of cost benefits from clinical pharmacy services, which could encourage state Medicaid programs, other payers, and DSH hospitals to invest in these services.** If the “truth” is that clinical pharmacy services not only improve outcomes but also can stretch our health care dollars farther by producing better outcomes for the same dollars, or could even save money overall, then the failure to demonstrate that truth in a convincing manner may be carrying a high financial and human cost each month that this information remains unknown. Chapter III provides three specific types of research opportunities that would contribute to this knowledge. However, since no single study could answer all the questions necessary to optimize clinical pharmacy services, consideration should also be given to developing a mechanism for supporting selected organizations to focus on clinical pharmacy services research over the longer term, perhaps as part of a focus on the larger topic of research on medication use system quality and safety. One existing model for this is HRSA’s Office of Rural Health Policy’s Rural Health Research Centers, which have vastly increased the knowledge base on rural health and health care.

To address the special challenges faced in rural areas:

- 3. Explicitly consider the unique aspects of rural safety-net providers and pharmacy service delivery in rural communities within the general options outlined in this report.** Most of the options described in this report could promote expansion of clinical pharmacy services in both urban and rural settings. However, different methods may be needed to make these efforts effective to these different audiences. Thus, when considering action on any of the options outlined in this report, the need for unique implementation strategies based on urban vs. rural audiences or based on safety-net provider type (FQHC/DSH hospital vs. RHC/CAH) should be considered.
- 4. HRSA can encourage inclusion of clinical pharmacy services as part of supported telepharmacy projects** through its Office of Health Information Technology, to increase the future ability of residents of remote areas to access clinical pharmacy services.
- 5. HRSA can consider altering existing programs such as the National Health Service Corps (NHSC) and Area Health Education Centers (AHEC) programs to more explicitly support the integration of clinical pharmacy services into rural as well as other safety-net organizations.** Several existing federal programs that support rural health care services do not explicitly support development of clinical pharmacy services, but could. For safety-net providers to recognize the importance of making high-quality clinical pharmacy services a core element of their programs, federal initiatives should seek to be aligned with sending this message directly and indirectly. While

opportunities to strengthen the AHEC and NHSC programs with respect to support of clinical pharmacy services were highlighted in the background research for this report, it is notable that both were also highlighted by the 2006 National Advisory Committee on Rural Health and Human Services in their "Report to the Secretary." A forthcoming report evaluating a demonstration to include pharmacists in the NHSC can inform HRSA's decision with respect to inclusion of these professionals.

To otherwise encourage clinical pharmacy services in safety-net providers participating in HRSA-funded programs:

6. **Continue to look for opportunities to raise expectations for clinical pharmacy services in safety-net providers that participate in HRSA-funded programs.** HRSA has already elevated its attention to safe medication use in safety-net providers, for example, by identifying and disseminating best practices. HRSA may identify other opportunities to raise expectations for clinical pharmacy services. For example, the National Quality Forum (NQF) has a Therapeutic Drug Management Quality Project underway that has produced draft preferred practices. HRSA may find opportunities to build on the NQF's work through the routine evaluation of safety-net providers by its Office of Performance Review. Also, HRSA could begin to expect clinical pharmacy services to be built into FQHC new starts and expansions, where the anticipated patient mix includes a substantial volume of patients with chronic conditions.
7. **Look for opportunities to encourage stronger relationships between colleges of pharmacy and safety-net providers.** As many of the case study discussions and the prior Evaluation of the Clinical Pharmacy Demonstration Program suggest, establishing strong partnerships with colleges of pharmacy has been and remains a promising way to initiate or expand clinical pharmacy services in safety-net settings, both by providing financial stability for the programs and, in the longer term, by helping to provide a stable supply of pharmacists trained to provide clinical services in safety-net settings. HRSA may find opportunities to influence the development of relationships between colleges of pharmacies and safety-net providers, for example, it could consider reshaping existing awards programs, such as the student chapter awards program sponsored by the Pharmacy Services Support Center, to provide recognition and financial rewards to pharmacy schools with the strongest relationships with safety-net providers.
8. **Compare improvement results from HRSA-sponsored disparities collaborative teams that do and do not include pharmacists; if the results are favorable for teams with pharmacists, HRSA could actively disseminate this information and encourage the inclusion of pharmacists on the teams.** Hundreds of FQHCs have participated in disease collaboratives that have worked to improve care for conditions including asthma, diabetes,

depression, and cardiovascular disease, all conditions where the value of pharmacist intervention has been shown in the literature. However, to our knowledge, no study has directly compared results of disease management initiatives with and without pharmacists. If positive for the teams with pharmacists, HRSA would be in a position to directly link two important quality improvement efforts—efforts to advance clinical pharmacy services and disease management to reduce disparities.

OPTIONS FOR FOUNDATIONS, STATES, AND PROFESSIONAL AND PROVIDER ASSOCIATIONS

The preceding steps taken by the federal government in and of themselves will not be enough to result in the provision of a high level of clinical pharmacy services in safety-net settings. Other key players include foundations, state Medicaid agencies, and professional and provider associations.

1. Foundations could partner with the federal government to sponsor studies to help fill the information gap regarding the cost benefits from these services. Foundations could also provide start-up or ongoing financial assistance for clinical pharmacy services for interested safety-net providers who have used a financial planning tool and optimized existing sources of revenue.
2. State Medicaid agencies can decide to amend their state plans to pay for clinical plans services, or include clinical pharmacy services as a part of a larger waiver application they may be planning. Similarly, Medicaid managed care plans set their own payment policies and could choose to begin paying for these services.
3. National organizations concerned with Medicaid such as the National Academy for State Health Policy, National Association of State Medicaid Directors, National Governors' Association, and Center for Health Care Strategies Purchasing Institutes can help share experiences from the states that currently pay for clinical pharmacy services with other states, particularly as second-generation efforts such as those in Missouri and Florida become fully implemented.
4. With sponsorship, The American Association of Colleges of Pharmacy could further its existing activities to create national networking opportunities between schools that have partnered with safety net organizations and those that have not. Strong academic-safety net partnerships can be more formally highlighted to increase the awareness of schools about the value to schools and communities engaged in this work. Furthermore, there may be ways in which existing AACP programming could be leveraged to support further expansion of these academic-practice partnerships.
5. The National Association of Chain Drug Stores (NACDS) can work with its members to further build on the contractual relationships established to date between FQHCs and other safety-net providers and chain drug stores. Almost

2,000 contractual relationships have been established between safety-net providers and independent and chain drug stores, with the assistance and encouragement of HRSA's Pharmacy Services Support Center. With encouragement from the NACDS, many more of these contracts could be established with chain drug stores, and they could be used to provide clinical pharmacy services as well as traditional pharmacy services.

6. The National Association of Community Health Centers (NACHC), National Association of Public Hospitals (NAPH), and other safety-net provider organizations can educate their members about the value of these services.
7. National pharmacy associations that currently provide awards to schools of pharmacy for program recognition or scholarships can include specific recognition or awards to schools with strong relationships with safety-net providers.
8. The state Boards of Pharmacy can increase their approval of telepharmacy networks in order to establish traditional and clinical pharmacy services for patients in remote locations.

CONCLUSION

In summary, clinical pharmacy services seem to hold great promise for improving the health of the many patients with chronic conditions who visit safety-net providers. The safety-net providers who have sustained these services are strongly committed to them because they find high value for patients and physicians. Further, some studies suggest clinical pharmacy services may stretch health care dollars further by producing better outcomes for the same cost, or may even save money for the health system overall. Federal actions in concert with efforts by private-sector organizations could improve the availability of clinical pharmacy services, through efforts to generate broader awareness of the benefits of these services found by the safety-net providers who do offer them, attention to opportunities to strengthen existing HRSA programs' emphasis on clinical pharmacy services, and encouragement of stronger linkages between schools of pharmacy and safety-net providers. Additional evidence of return on investment would be helpful to convince payers to extend payment for these services, and thus make these services financially sustainable across safety-net providers on a widespread basis.

CHAPTER I

INTRODUCTION

A. RATIONALE AND PURPOSE FOR THE REPORT

This report to HRSA recommends how to generate improvements in the use of clinical pharmacy services across all HRSA programs in which medication plays an integral role in patient care. HRSA commissioned the report to support its response to the request made by the Senate Committee on Appropriations for a report on this topic (Report 109 287, July 26, 2006). The Committee's request was prompted by findings of the Mathematica evaluation of the HRSA clinical pharmacy demonstration projects that these services proved valuable to patients, health centers, and colleges and schools of pharmacy that participated in the study.

In requesting the report, the Committee specifically voiced the expectation that HRSA collaborate with external organizations such as the American Association of Colleges of Pharmacy, the National Association of Community Health Centers, and members of the 340B Coalition to develop the recommendations. Further, the committee noted that the recommendations should include options for financing clinical pharmacy services in HRSA-supported programs, cost of such financing, and opportunities for maintaining and building upon the relationships with colleges and schools of pharmacy.

The need for improved medication safety has never been clearer. The Institute of Medicine reports that medication errors injure 1.5 million people per year and cost billions of dollars annually (IOM 2006). One estimate found that for every dollar spent on ambulatory care medications, another is spent to treat new health problems caused by the medications (Alliance for Aging Research 1998, Johnson and Bootman 1995). Further, the cost and human burden of chronic conditions such as diabetes, dyslipidemia, hypertension, and asthma, where medication is a critical part of treatment, continue to grow. The underserved populations served by safety-net providers tend to have a higher prevalence of these diseases than other populations of similar age and gender, making these issues at least as salient for safety-net providers as for others.

The services provided by clinical pharmacists are critical to meet the needs of improved medication safety. The American College of Clinical Pharmacy has defined clinical

pharmacists (PharmDs, or Registered Pharmacists with additional training) as “experts in the therapeutic use of medications...and a primary source of scientifically valid information and advice regarding the safe, appropriate, and cost-effective use of medications.” Clinical pharmacists provide care for patients in all health care settings and usually work as part of an inter-professional health care team to provide individualized patient care consistent with clinical guidelines. Clinical pharmacy services generally include the management of medication therapy and the appropriate use of medications and medical devices.

The role of the clinical pharmacist is relatively new to the health care system with pharmacists taking on a more clinically oriented role in the mid 1990’s. Since 2005, all graduating pharmacists bring six to eight years of training that includes the ability to identify and resolve medication problems, whether they originate with the health system (such as prescribing errors) or with the patient (such as not taking a key medication due to its cost or an adverse effect). Therefore, a substantial and increasing number of the estimated 232,000 active pharmacists in the U.S. have advanced clinical training to improve appropriate use of medicinal drugs, which are the first line of therapy in today’s health care delivery system (Knapp and Cultice, 2007). The median expected salary for a typical clinical pharmacist is currently \$91,400 (Salary.com online 2008).

Further, studies show clinical pharmacy services can add value by improving clinical outcomes for a range of conditions where medication plays an integral role, including diabetes, dyslipidemia, asthma, hypertension, depression, and patients on anticoagulation therapy (see Appendix A for a summary of the literature). Though evidence is more limited regarding economic outcomes, existing studies point to savings from reduced hospitalizations and emergency department visits, or cost neutrality along with improved clinical outcomes, when all health care costs are considered.

Despite their value, clinical pharmacy services are infrequent among safety-net providers today. For purposes of this report, clinical pharmacy services are services provided by a clinical pharmacist that go beyond the dispensing of drugs and serve the purpose of promoting safe, effective care, and achieving desired therapeutic outcomes through collaborative participation in patient-specific medication and disease management. HRSA recognizes that other types of providers can also play important roles in creating an overall environment of medication use safety within safety-net organizations, and this broader topic will be a component of a major patient safety collaborative undertaken by HRSA to identify and spread best practices in patient safety.

This report provides options and opportunities for advancing clinical pharmacy services among safety-net providers who participate in HRSA-supported programs (Chapter III). The options include actions the federal government and others—including state Medicaid agencies, professional and provider associations, and foundations—can take to facilitate expansion of these services. The report also provides findings from extensive interviews with safety-net sites and other relevant organizations (see below for methods) and reflects on clinical pharmacy services in safety-net providers—why some safety-net providers have implemented these services, their experiences to date, what the barriers are to more widespread implementation of clinical pharmacy services, and rural considerations (Chapter

II). The remainder of Chapter I summarizes the methodology/approach used to develop the report.

B. METHODOLOGY/APPROACH

With funding from HRSA, Mathematica Policy Research, Inc., and its partner, the University of Minnesota, developed the information for this report using the following methods and data sources:

- **Case study discussions were held with safety-net providers who currently provide clinical pharmacy services.** We talked with administrators and pharmacists at seven federally qualified health centers (FQHCs), five AIDS Drug Assistance Program (ADAP) sites, and six disproportionate share hospital (DSH) sites. (Please see Appendix B for definitions of these types of safety-net providers.) The following major interview topics were discussed using semi-structured protocols tailored to each type of safety-net setting: (1) what prompted them to provide these services, (2) how the services are structured, (3) how they financed their services, (4) obstacles they faced in initiating and sustaining clinical pharmacy services, (5) benefits that the sites and their patients have realized, and (6) relationships with schools of pharmacy or others that have contributed to their ability to provide these services.
- **A meeting of national stakeholders was convened** to obtain their input on the best strategies for advancing clinical pharmacy services in safety-net settings. Representatives from a total of 20 organizations attended, including safety-net provider organizations such as the National Association of Community Health Centers (NACHC), pharmaceutical organizations such as the National Association of Chain Drug Stores (NACDS), professional associations such as the American Pharmacists Association (APhA) and the American Society of Health-Systems Pharmacists (ASHP), academic representatives from the American Association of Colleges of Pharmacy (AACCP), and other members of the 340B coalition. Follow-up calls to other important organizations that could not attend, including the National Rural Health Association and the National Quality Forum, were also helpful.
- **Data from HRSA's Uniform Data System were analyzed.** The UDS provides service, utilization, and financial characteristics of FQHCs that help us assess the potential for expanding clinical pharmacy services among safety-net providers.²

² Analyses of UDS data included all FQHCs offering primary care in at least one year-round service site. Of the grantees that met these criteria, 92% were community health centers. The remaining 8% included county health departments, migrant health centers, and clinics that focus on care for the homeless.

- **FQHCs were mapped in relation to schools of pharmacy** to assess the potential for extending clinical pharmacy services via stronger ties between pharmacy schools and FQHCs (such as through co-funded faculty positions and precepting pharmacy students at FQHCs).
- **Interviews were conducted with nine colleges of pharmacy**—some that have relationships with safety-net providers and some that do not—to explore the possibilities for building stronger relationships between schools of pharmacy and safety-net providers.
- **Interviews were held with state Medicaid agencies.** Because Medicaid is typically the largest payer for safety-net providers, interviews were conducted with seven state Medicaid agencies that pay for clinical pharmacy services, and with seven state Medicaid agencies that do not currently pay. Information available from journals and the Internet was reviewed for one state that pays, but whose staff were not responsive to our requests for an interview. Topics for those who pay for clinical pharmacy services included the motivation for this payment policy, structure of payment, context (for example, is the payment embedded within a larger program), implementation challenges, and the clinical and financial benefits they have realized. The interviews with states that do not currently reimburse for clinical pharmacy services focused on their receptivity to adding payment for these services in the future.
- **An interview (or e-mail) was held with (sent to) three Medicaid-focused managed care organizations,** facilitated by the Association of Community Affiliated Plans (ACAP), to obtain information on the extent to which their Medicaid managed care plan members pay for clinical pharmacy services, the types of information that would encourage them to begin to pay for these services, and more broadly their thinking about the role of the pharmacist in improving health outcomes for their members.
- **A focus group was convened with financial and executive administrators, and with clinical and pharmacy staff from FQHCs** to better understand their decision-making processes and key concerns as they consider investment in clinical pharmacy services. These individuals provided input on the types of information needed to support decisions about implementation of clinical pharmacy services, as well as input towards the development of an interactive, web-based tool designed to assist local safety-net providers in planning for clinical pharmacy services. The focus group meeting was held in August 2007; the web-based tool is being tested in winter 2007-8.
- **Internal discussions of the insights from the two pharmacy consultants on the team were held.** The discussion was based on their field experience and their ongoing, routine communications with safety-net providers about pharmacy issues.

CHAPTER II

FINDINGS AND CONSIDERATIONS

A. CASE STUDIES: FACTORS THAT FACILITATED IMPLEMENTATION AND EXPERIENCES TO DATE

Some safety-net providers, such as the selected FQHCs, DSHs, and ADAP sites interviewed to prepare this report, have been able to finance and sustain clinical pharmacy services. This section explains what prompted these sites to initiate clinical pharmacy services, and what financing mechanisms they have used, first across all the types of sites and then noting differences by type of site (FQHC, DSH, or ADAP site). Self-reported outcomes from the programs are summarized, and several programs that reported striking success are highlighted. Appendix C provides more details about all of the case study sites' programs and reported outcomes.

1. **Clinical pharmacy services were initiated when one or more individuals became a champion for them and when funding was identified.** External start-up funding targeted to clinical pharmacy services was most critical for the FQHCs. Seed money from HRSA's Clinical Pharmacy Demonstration Program (CPDP) in the early 2000's was a critical factor leading to initiation of clinical pharmacy services in the FQHCs. It served both as a means to focus organizations' attention on the potential usefulness of these services, and as a means to cover costs for a start-up period that usually included recruitment of a pharmacist, detailing of collaborative protocols between the pharmacist and physicians that specify what the pharmacists will do, sometimes new equipment for patient monitoring, arranging space for patient consultation, and the pharmacist's salary during a period where the new pharmacist develops trust and working relationships with clinicians and builds up the volume of patient contacts. The second critical factor was the presence of one or more individuals who championed the services. The initial champion can be either in the FQHC or in a college of pharmacy, the sites' experiences suggest: the sites were about evenly split as to whether the FQHC or the college of pharmacy had initiated the grant application process.

In the ADAP sites, Ryan White grant funding did not specifically target clinical pharmacy services for funding as the CPDP program did, however, it was available to be used as both start-up and ongoing financing for the services to HIV/AIDS patients when one or more champions for the services emerged and looked for funding sources. More so than with other conditions, the focus of clinical pharmacy services for HIV/AIDS patients tends to be on improving adherence to the complex medication regimens that are required to suppress the virus.

In the case study DSHs, physicians tended to demand clinical pharmacy services, and the hospitals saw potential to contain costs as well as improve patient care on high volumes of high-risk, high-cost patients. Since hospitals generally have much larger budgets than primary care sites, and since they may have the potential to capture some savings through fewer hospitalizations or emergency visits by indigent patients, the hospitals did not seem to need external start-up funding.

2. **Once clinical pharmacy services were established, the case study organizations worked to retain them, financing them using their own general revenue funds, help from colleges of pharmacy, grants, and to a lesser extent patient billing.** Once the clinical pharmacy services were established, many health centers found ways to sustain them long-term beyond the end of the grant, despite a difficult financial environment, because they perceived them to be so valuable for their patients.³ *In no case did the clinical pharmacy services generate enough revenue to cover costs.* Use of grants as a financing mechanism was common to all the ADAP sites (primarily Ryan White funds), whereas few of the other sites financed their services with grant funding. Conversely, use of revenue from pharmaceutical dispensing and/or general budgets of the organizations was very common among FQHCs and DSHs (all but two of the 13), whereas only one of the ADAP sites used these revenue sources.

Both DSHs and FQHCs benefited from university partner funding, but only one ADAP site did so. DSHs also usually billed Medicare part D for medication therapy management (MTM) services, whereas this was less common among the FQHCs and ADAP sites (only two and zero did so, respectively).

3. **Clinician support was critical to success.** At the case study sites, most of the physicians were reported to actively support the clinical pharmacist(s) by referring their patients to them, which appears to be key to the organizations'

³ At least one health center in half of 18 original CPDP networks that implemented clinical pharmacy services sustained the services into 2007 (about 4 years after the end of the grant period). Of the others, some could not sustain the services without external financing, and a few of these FQHCs that pioneered clinical pharmacy services had implementation issues that caused them to discontinue services after the grant period.

decisions to initiate and sustain these services, as well as critical to reaching the patients who need the services. Initially, many of the FQHC sites in particular cited physician resistance to the services, largely a function of some physicians not wanting anyone else to take care of their patients. Such resistance was typically overcome through some combination of (1) documenting and reporting improved patient outcomes to providers, (2) beginning the program with voluntary first-adopters, who then promoted the services to their colleagues, (3) hiring new provider staff who were supportive of the clinical pharmacy program, and (4) more general education and presentations by clinical pharmacists at staff meetings to inform other providers about their role and services.

4. **Finding space to provide clinical pharmacy services was a struggle for many of the safety-net sites.** Pharmacists who meet individually with patients need private meeting space to respect patients' rights to privacy. Allocating this space has been difficult for safety-net providers, some of which are quite physically space-limited relative to the needs of their patient populations. One we spoke with described how alternative uses of space are considered by management using a business perspective; since clinical pharmacy services generate little revenue, they are given low priority for space. Physician support has sometimes been key to resolving this issue, by generating the organizational will to reallocate or reorganize existing space. In one case, space was able to be incorporated into plans for an expansion.
5. **Those sites that had tracked outcomes for patients who received clinical pharmacy services reported positive outcomes, reinforcing the conclusions of the earlier *Mathematica* study.** Seven of the sites interviewed for the study were able to quantify some of the clinical outcomes of their clinical pharmacy services, and all reported positive results.⁴ For example, two clinical pharmacists at El Rio Community Health Center in Tucson, Arizona, focus on patients with diabetes. El Rio reports finding the percentage of patients with good HbA1c control increases dramatically after receiving the services—almost seven-fold, from 6 percent to 41 percent by one count (Leal et al. 2004). El Rio was one of three of the case study FQHCs that compared their diabetes patients who received clinical pharmacy services to patients with diabetes in a comparison group, and all three found that their positive results held up to this more rigorous test (Hogan et al. 2006, Scott et al. 2006, Shane-McWhorter and Oderda 2005).

Two of the DSH hospitals reported cost savings (the others had not tracked this). Harris County Hospital District (HCHD), in Houston, Texas, reports documenting \$1.5 million in cost savings in 2005 alone from emergency department and hospital visit reductions in the diabetes population who received clinical pharmacy services, compared to

⁴ The others were not tracking outcomes at the time of our interviews.

patients who were scheduled for these services but did not keep their appointments. HCHD's program includes eight pharmacists who are located in community health centers and work based on physician referrals for patients with any chronic disease, as well as one who specializes in HIV and one anticoagulation specialist. Grady Health System, in Atlanta, Georgia, reports that clinical pharmacy services in their heart failure clinic were estimated to save more than \$200,000 over a 5-month period, and they identified approximately \$660,000 per year savings from reduced hospitalizations due to outpatient clinical pharmacy services for deep vein thrombosis (DVT). Grady's program includes three clinical pharmacists and one resident, who are each assigned to a primary care clinic, and who provide clinical pharmacy services targeting a wide range of conditions including HIV, diabetes, DVT, hepatitis C, heart failure, and lipid problems.

Only one of the ADAP case study sites had documented some of its outcomes. In Westside Community Health Services in St. Paul, Minnesota, 82 percent of the HIV/AIDS patients who received adherence-focused services from a pharmacist showed viral suppression (HIV RNA \leq 75 copies/ml using the Versant HIV-1 RNA v3.0 test), compared with only 57 percent of the patients who did not receive the services (Gengler 2005). Thirty-one patients participated in the study. In a separate effort, a clinical pharmacy resident documented and resolved 55 drug therapy problems in just 16 patients with arthritis (Skoglund 2005).⁵

Several sites also noted that having the clinical pharmacists helps free up physicians to be able to better meet high patient needs in the area.

B. BARRIERS TO WIDESPREAD IMPLEMENTATION OF CLINICAL PHARMACY SERVICES

1. The benefits recognized by safety-net providers that have implemented clinical pharmacy services have not been effectively disseminated to the administrators and medical providers in other safety-net organizations.

Specifically, several staff of colleges of pharmacy cited safety-net provider administrators' lack of awareness of the potential benefits of clinical pharmacy services as a barrier to further expansion of relationships between the schools and those sites. In the focus group of FQHC staff, some were previously unaware of the potential benefits of these services. Many of the safety-net providers interviewed for the study indicated that their physicians tended to be skeptical at first regarding the value of clinical pharmacy services for them and their patients, but most were won over as they saw their patients' conditions improve and some of their time freed up to see more patients. Those who attended the national stakeholders meeting also believed that physicians and administrators of safety-net organizations are unaware of the potential benefits of clinical pharmacy services. Logically speaking, without active interest in these services, they will not materialize.

⁵ More detail about the clinical pharmacy services and their context in El Rio, HCHD, and Westside is found in Appendix D.

In addition, schools of pharmacy were a source of knowledge and financial support for many of the safety-net providers interviewed for the study (including four of the seven FQHCs and three of the six DSHs), but currently, the type of collaborations that extend to cofunding a faculty member with the safety-net site—which adds the most value for the safety-net provider—are relatively infrequent. Most of the pharmacy schools interviewed for the study were not involved with safety-net providers in this way. Also, schools of pharmacy interviewed for the study often did not think about safety-net settings as offering a unique educational opportunity for their students; instead, they tended to view them as similar to any other experiential training setting. For example, in one training program we discussed, although the students work on-site at an FQHC, they are not taught about the 340B program or how the safety-net organization works to provide access to its low-income and uninsured patients. However, when this was raised during the interview, the respondent was interested in the idea that these sites could offer a unique experience to prepare students to be able to serve the part of the healthcare system that provides care for the uninsured.

2. The limited ability of safety-net providers to bill for clinical pharmacy services is the largest barrier to their expansion.

Indigent patients and Medicaid patients comprise the lion's share of the patient population for safety-net providers. Seventy-five percent of FQHCs' patients are covered by Medicaid or uninsured. At present, only a few state Medicaid programs pay for clinical pharmacy services, and in general they tend to be narrowly targeted programs that have reached relatively few people. State Medicaid programs that do pay for clinical pharmacy services often do not include Medicaid managed care in their programs, although the health plans that serve this population set their own payment policies and could choose to pay for these services. Capitated Medicaid managed care includes about 36 percent of Medicaid beneficiaries nationally, and represents an important payer for many safety-net providers. Three Medicaid-focused health plans that provided information for this report did not pay for clinical pharmacy services at the point of care, but they are open to the idea of doing so in the future, if shown evidence that such services improve quality while maintaining cost neutrality are not cost saving.

Some safety-net providers are able to bill Medicare Part D for Medication Therapy Management (MTM) (including some of the FQHCs and most of the DSHs interviewed for the study), but our consultants report several issues that have kept this from effectively supporting clinical pharmacy services among safety-net providers. The most significant limiting factors include size of the eligible population and required billing mechanisms. Most primary care-focused safety-net providers (such as FQHCs) do not serve a large Medicare population, and restrictive eligibility criteria for MTM further limit the number of patients qualified for service delivery in a relatively small pool. Additionally, provisions for serving as an MTM provider in Medicare Part D are usually embedded within traditional pharmacy contracts focused on medication dispensing services, thus making it challenging for organizations that do not operate licensed pharmacies to receive compensation for MTM services. Approximately two-thirds of FQHCs do not operate licensed pharmacies, but these organizations could still potentially provide clinical pharmacy services.

Billing under Medicare Part B is, for the most part, limited to “incident to” billing, which carries requirements that some find restrictive, and reimbursement rates that are quite low relative to the usual lengths of patient visits reported by pharmacists who provide these services. DSH hospitals may also be able to bill their Medicare Part B facility fee for patients seen by clinical pharmacists, although only two of those interviewed for the study reported doing so. At the end of the Clinical Pharmacy Demonstration Program, many demonstration sites discontinued or scaled back their clinical pharmacy services as a result of the very limited ability to bill for them (Felt-Lisk et al. 2004).

Why is financing so constrained? Medicaid agencies, other payers and DSH hospitals may be less interested in expanding these services than they would be with stronger evidence that they produce better results for the same dollar, or that they save money overall. The stronger studies that exist have been encouraging in that they have reported at least better clinical results at no net cost increase, and the literature review found two—one in a Medicaid program and one in a university-affiliated clinic focused on anticoagulation patients—that reported overall cost reductions (Lai and Sorokin 1998, Chiquette et al. 1998). Some others have also reported significant reductions in the number of emergency department visits and/or hospitalizations relative to a control group, a positive sign for cost reduction even if total costs were not measured or were too variable to draw firm conclusions. However, overall, the study designs of the literature that examines cost savings from clinical pharmacy services have been relatively weak. (See Appendix A for a summary of the stronger literature.)

Medicaid agencies interviewed for the study that were not currently paying for clinical pharmacy services were aware in a general sense of the existence of clinical pharmacy/medication therapy management services, but were not specifically aware of the clinical benefits that clinical pharmacy would bring. Also, they indicated that information on the return on investment from these services would be important in any future decision about adopting them.

DSH hospitals as well as payers may be less interested in initiating or expanding clinical pharmacy services without stronger evidence of cost neutrality with better outcomes, or net savings. At least in theory, DSH hospitals benefit directly from lower uncompensated care costs if indigent patients required fewer hospitalizations or emergency visits, as was reported by two of the case study sites. The extent of benefits from such reductions depends in part on state-specific Medicaid DSH formulas: if such formulas are tightly tied to current utilization of services by indigent patients, then the hospital may experience reduced revenue corresponding to reduced costs. However, in many states, the formula may not be tightly tied to utilization in the same year, which opens the door to savings at least in that year if the hospital’s costs are lower than expected. Further, several DSH sites interviewed for the study stated that desire for cost-containment for indigent patients was a reason they instituted clinical pharmacy services. Clinical pharmacy services provided in the outpatient setting to indigent patients in some of the DSH hospitals interviewed for the study are not easily tracked since no bill is paid. This makes it difficult to analyze the return on investment such hospitals may see if those patients do not require as many hospitalizations or emergency visits. This along with a lack of studies specific to DSH hospitals means there is

II: Findings and Consideration

scant concrete evidence to show other DSH hospitals that such services could result in savings to them.

3. Finances other than patient revenue used by the study's safety-net providers to support their services are not available for many safety-net providers, particularly many FQHCs.

While several of the FQHCs interviewed for the study supported their clinical pharmacy services in part with general revenue, only about a third of FQHCs had positive net revenue for both 2005 and 2006, and for those that do have enough revenue in a given year to invest in some additional services, there are many competing needs. About 21 percent of FQHCs had positive net revenue in both 2005 and 2006 sufficient to support about half a pharmacist's salary, and had moderate to high numbers of patients with chronic conditions (who are the primary target population for clinical pharmacy services). Second, while some used surpluses generated by their pharmacy's dispensing function, about two-thirds of FQHCs have no pharmacy.⁶ Opportunities to generate surpluses under a contractual pharmacy arrangement may exist, but one might expect them to be more limited. Third, while some safety-net sites had been able to use grants to help support their clinical pharmacy services, this was relatively rare among the FQHCs and DSHs, since funders were said to generally prefer providing seed money rather than funding ongoing services. Finally, approximately half of FQHCs are located more than 60 miles from a school of pharmacy, a significant limitation in creating partnerships that involve the direct sharing of faculty members and student trainees across locations.

ADAP sites that are Ryan White grantees may be relatively better able to access supporting grant funds by utilizing Ryan White funds to provide clinical pharmacy services for people with HIV/AIDS, although we have not studied the tradeoffs to other services that could result. Also of note, not all ADAP sites are Ryan White grantees, so not all would have that option. DSH hospitals may have a different advantage over FQHCs in that they are often already affiliated with a university, and so may find it easier to leverage that relationship for support. Further, their ability to capture at least some savings from reducing hospitalizations and emergency visits by indigent patients along with their typically larger Medicare populations receiving Part D relative to FQHCs means they may have less need for subsidization.

4. The inability of primary care safety-net settings to capture much of the savings that are likely to occur probably presents a barrier to service expansion in these settings.

Those who attended the stakeholders' meeting generally believed that clinical pharmacy services are likely to result in overall cost reductions to the health care system (whether or not these reductions are fully documented), but that it is reduced hospitalizations and

⁶ The success of one clinical pharmacist at an FQHC with no licensed pharmacy suggests this is a model that can work (Shane-McWhorter and Oderda 2005).

emergency visits that drive cost reductions—and primary care safety-net organizations cannot capture savings that result from those factors. The literature reviewed for the study shows a pattern consistent with their belief: savings from reductions in hospitalizations and emergency visits, with more mixed results regarding the effect on clinic visits (including visits to the pharmacist) and drug costs. Although some of the safety-net providers interviewed for the study mentioned that increases in physician productivity occurred as a result of the pharmacists' services (the physicians are freed up some to see more patients, potentially enabling them to generate more revenue for the health center), this was not quantified by any of the sites or in any of the studies we found.

5. The difficulty of recruiting pharmacists interested in working in safety-net settings presents a barrier to widespread expansion of clinical pharmacy services at safety-net sites, attendees at our national stakeholders meeting believed.

Nearly half of the DSHs and FQHCs interviewed for the study that had sustained clinical pharmacy services reported some difficulty with recruiting or retaining their pharmacists. Those attending the national stakeholders meeting pointed out that overall, pharmacists are in relatively short supply, along with nurses and physicians, and that an increase in demand for clinical pharmacists in safety-net settings would likely clash with a supply that is relatively limited, overall.

Also related to supply issues, some state Medicaid programs that pay for clinical pharmacy services have found fewer-than-expected pharmacists who are interested in providing clinical pharmacy services under their programs. Missouri, Minnesota, Mississippi, and Iowa have all found recruiting pharmacists into their programs difficult (or reported low numbers of participating pharmacists). One state suggested this is due in part to the prevalence of pharmacists who completed their training prior to the mid-1990s, when clinical pharmacy became part of the regular curriculum for pharmacy students. Many of these older pharmacists may simply not be interested in providing clinical pharmacy services, a factor that should self-correct as new cohorts of pharmacists continue to enter the workforce. Dispensing is also generally a more lucrative function, and the state perceived that many pharmacists are very busy with existing responsibilities.

C. CONSIDERATIONS SPECIFIC TO RURAL SAFETY-NET PROVIDERS

Safety-net organizations clearly span both urban and rural settings and while many of the findings presented in this report are relevant in both settings, there are some greater challenges facing those entities that operate in rural communities. For FQHCs and DSHs, most of the issues related to the logistics of capturing revenues via Medicare and Medicaid are the same between urban and rural areas. However, the issues and potential solutions for expanding clinical pharmacy services in rural safety-net organizations such as critical access hospitals (CAH) and rural health clinics (RHCs) are somewhat unique due to geographic distribution and the unique ways in which these entities interface with payers compared to other safety-net organizations. (Please see Appendix B for definitions of these safety-net providers.)

Despite the six challenges identified below, some rural safety-net organizations have successfully found ways to address and overcome these challenges, and report positive outcomes for the organization and the community served. Two examples were identified as this report was being developed; they are highlighted in Box 1.

BOX 1: REPORTS FROM THE FIELD—SUCCESS REPORTED BY RURAL SAFETY-NET PROVIDERS

Tyler Health Care Center (THCC), Tyler, MN

Background: THCC comprises a 20-bed critical access hospital, rural health clinic, and long-term care facility located in a community of 1,250 residents.

Clinical Pharmacy Services: Recently successfully expanded the role of the pharmacist in the organization, moving from approximately 0.1 FTE of contracted pharmacist time devoted solely to inpatient dispensing services to hiring a 1 FTE position where the pharmacist oversees inpatient medication distribution systems and provides clinical pharmacy services in both inpatient and outpatient settings.

Patient Safety and Clinical Outcomes Reported (self-reported data from THCC): Improved patient safety systems in the inpatient facility (three distinct medication safety practices have been implemented), improved clinical outcomes (pharmacist management of anticoagulation resulted in a nearly 20 percent increase in the number of patients being managed within treatment goals).

Other Reported Outcomes: Improved physician satisfaction via collaborative patient care delivery, and improved ability to recruit pharmacists to the organization and community (successfully recruited two newly graduated pharmacists to the area in the last four years).

Paynesville Area Health Care System (PAHCS), Paynesville, MN

Background: PAHCS comprises a 20-bed critical access hospital, seven primary care clinics serving eight communities, 120 long-term care beds, and an assisted living facility.

Clinical Pharmacy Services: Clinical pharmacy services have been delivered in the primary care clinic setting since 1995.

Patient Safety and Clinical Outcomes Reported (self-reported data from PAHCS):

- 92 percent of diabetes patients seen by pharmacist test blood sugars vs. 10 percent of those not seen by pharmacist
- Diabetes patients seen by pharmacists are more likely to have lab tests to monitor diabetes and have clinic follow-up
- Patients managed by pharmacists have improved blood sugar control (HbA1c decreased by 1.4 with average of 6.6 percent)
- 89 percent of anticoagulation patients managed by pharmacists are within therapy goal range vs. 50 percent of those not seen by a pharmacist
- 98 percent of PAHCS patients feel health outcomes are improved with pharmacist involvement

Other Reported Outcomes: Physician satisfaction is improved. One provider noted, “Our PharmDs are able to spend the time needed to appropriately educate our patients, leaving time for me to see more patients.”

1. **A lack of awareness of potential benefits of clinical pharmacy services, particularly in the ambulatory care setting, among rural health organizations.** This issue has been highlighted above, but it is reiterated here as it is potentially a barrier that is more prevalent in rural areas. In particular, nearly all of the research that has been conducted with respect to pharmacy services delivered in rural health care organizations has focused on inpatient services only. Through the course of research completed to prepare this report, there were very few examples identified where rural health care organizations have moved beyond inpatient services to integrate pharmacists into the full scope of their services.

2. **Maldistribution of the pharmacy workforce across urban and rural communities.** Individuals living in rural communities represent roughly 25 percent of the United States population, however only 12 percent of pharmacists practice in rural areas (Epstein 1996). Furthermore, populations in rural areas typically consist of a greater percentage of older patients compared to urban populations, a group that more heavily relies on health care resources, including pharmaceuticals (Larson et al. 2003, Gangeness 1997). Nationally, the ratio of pharmacists is 66 per 100,000 population in rural areas compared to an overall U.S. total of 78 pharmacists per 100,000 population (Knapp et al. 1997). As a result, expansion of clinical pharmacy services could be challenged by difficulties of recruitment and retention of pharmacists in rural communities. Yet, research suggests that to some degree, this distribution problem may not be solely related to geography, but rather to the type of practice opportunities sought by newly graduated pharmacists. The majority of practice positions in rural communities are associated with owning or being employed by independently owned pharmacies, however students from three colleges of pharmacy serving a rural region indicate that the availability of clinically focused, collaborative practice opportunities in rural health care organizations would increase their interest in practicing in a rural community (Traynor and Sorensen 2005). In this study, the most important factor limiting new pharmacist graduates' interest in existing rural pharmacy practice opportunities is the "work lifestyle" frequently associated with pharmacy ownership, specifically long hours and limited availability of relief help to allow for personal and professional leave.

3. **Limited adoption of medication safety practices in small rural hospitals.** A recent national study identified that only one-half of small rural hospitals surveyed had adopted four key medication safety practices (Casey, Moscovice, and Davidson 2005). Of importance for this report, it should be noted that the smallest hospitals of the surveyed group—many of which were Critical Access Hospitals—were even less likely to meet this standard. Another key finding of this report is that the longer hours a pharmacist spent practicing on site, the more likely the organization was to adopt or increase medication safety practices. This finding suggests that a first priority for rural safety-net providers may be a focus on using pharmacist time to address limitations in medication safety practices, before an emphasis can be placed

on delivery of clinical pharmacy services. In both of these areas, it is likely that rural safety-net providers would need to increase the amount of staff time provided by pharmacists within the organization.

4. **Limited adoption of technology for the purpose of providing clinical pharmacy services.** Background work for this report has revealed that the use of “telepharmacy” services is increasing in several areas of the country as a mechanism to maintain access to medications in remote rural areas where the size of the population is unable to support a traditional pharmacy or the local hospital is challenged in hiring necessary inpatient pharmacy staff. Some examples identified during the background research for this report include:

- Alaska provides clinical pharmacy services remotely to Alaskan natives.
- North Dakota State University College of Pharmacy has received \$2.5M in HRSA funding since 2002 to establish an extensive telepharmacy network that includes a total of 57 sites (13 hospitals and 44 health centers). This network is currently being used to provide traditional pharmacy services and medication reconciliation and disease education to patients in remote areas.
- Washington State University has partnered with the Community Health Association of Spokane (CHAS) to implement a telepharmacy program that includes student training. This could be a model for expanding relationships between Schools of Pharmacy and more remotely situated FQHCs.

While not necessarily the case in the above examples, in many cases where telepharmacy technology is being applied, it is being primarily used to support the core functions of a medication dispensing service, and not in a manner that supports the delivery of clinical pharmacy services directly to patients or in partnership with medical providers for the purpose of ensuring optimal drug therapy outcomes. It is anticipated that a key reason for this is that it is challenging to seek compensation from health care payers for tele-delivered clinical pharmacy services.

5. **Impact of Medicare Part D on financial viability of rural pharmacies.** Rural FQHCs are more likely to make pharmacy services available to their community via contract arrangements with local pharmacists/pharmacies rather than by maintaining on-site pharmacies. Additionally, many small rural hospitals contract with a local community pharmacist for delivery of inpatient services. The fiscal challenges created by Medicare Part D are contributing to the closure of a number of rural pharmacies, which in turn can impact service delivery within local safety-net organizations due to the interdependent nature of health care services in rural communities. The percentage of prescriptions moving from cash to being paid for by less profitable third-party payers (such as prescription drug plans) is higher in rural (18 percent) vs. urban areas (13 percent) (Fraher et al. 2005). For all pharmacies, this reduction in margin on prescriptions places a greater burden on non-medication related sales; however,

independent pharmacies—which comprise 48 percent of rural pharmacies vs. 29 percent of urban—are much more dependent on prescription medication sales revenue (93 percent) compared to chain stores (65 percent) (Fraher et al. 2005). Research has demonstrated that the closure of rural pharmacies results in significantly reduced medication utilization as well as increased travel distances to access services (Xiao, Sarofman, and Manasse 2000 a,b; University of Minnesota 2004-2005). The result is that the ability to maintain a financially viable practice has become disproportionately more challenging in rural communities, which in turn disproportionately challenges service delivery by rural safety-net organizations and health care access for rural residents.

6. **Academic-practice partnerships are uncommon between schools of pharmacy and rural safety-net providers.** In reviewing the literature on clinical pharmacy service delivery as well as through focused interviews with several colleges of pharmacy, formal collaborations between these institutions and rural safety-net organizations are limited at best. None of the individuals interviewed expressed familiarity with critical access hospitals or rural health clinics and none described significant relationships with organizations that might be categorized as such. Research has shown that health professionals are more likely to practice in a rural community if they have engaged in learning experiences in rural communities, thus formalizing relationships between academic institutions and rural health care organizations is likely a key element of supporting the workforce needs of these communities (University of Minnesota 2004-2005; Larson et al. 2003).

CHAPTER III

OPTIONS AND OPPORTUNITIES

Fostering the expansion of clinical pharmacy services requires addressing at least some of the multiple barriers described above. The federal government has some important levers with which to address barriers, but federal action alone will not result in widespread implementation of clinical pharmacy services among safety-net providers. Professional associations and state Medicaid agencies are other key actors.

A. FEDERAL OPTIONS

To improve awareness of benefits:

1. **Establish peer-to-peer networking and educational efforts, including support for providers to use a clinical pharmacy financial planning tool.** The Pharmacy Services Support Center (PSSC), funded by HRSA to support comprehensive pharmacy services among HRSA-funded providers, should consider establishing a peer-to-peer networking and educational effort for safety-net provider administrators and medical directors who are not familiar with the potential benefits of clinical pharmacy services. The effort could be designed to enable them to connect with peers who have successfully implemented these services and report positive experiences with clinical pharmacy providers. The PSSC could seek to include professional association partners, who maintain strong communication links to their members that could be used to encourage use of the service or educational materials once they are made available. Several of those who attended the national stakeholders' meeting believed this type of effort would be helpful to expanding the services.

Further, the PSSC could provide technical support to safety-net providers interested in establishing clinical pharmacy services, using the Clinical Pharmacy Financial Planning Tool developed by Mathematica Policy Research and partners under contract with HRSA. The tool is designed to assist providers in maximizing the potential of existing sources of support. PSSC consultants are

needed to help sites navigate parts of the tool that could not be standardized—for example, the potential for Medicaid revenues to support clinical pharmacy, given various state policies and program requirements, and the potential to optimize their savings from the 340B program as a resource.

With education and technical assistance, some additional safety-net providers may implement clinical pharmacy services by taking better advantage of existing financing opportunities. Regarding FQHCs, clinical pharmacy services appear highly relevant for many of them: UDS data for 2006 show 735 FQHCs that have a moderate to high number of patients with at least one of the following conditions often addressed by clinical pharmacists: diabetes, hypertension, asthma, heart disease, or HIV/AIDS. Further, about 1/3 of FQHCs with a licensed pharmacy are located within 30 minutes of a school of pharmacy; our interviews with schools seem to suggest that more of those schools may be persuaded to partially support these services, if made aware of the potential benefits to their mission and program. In the experience of our pharmacy consultants, many FQHCs could be better optimizing their use of the 340B program to create savings that could be used to help fund these services.

In all, about 21 percent of FQHCs had both net revenue for two years in a row sufficient to support about one-half a pharmacist's salary, and moderate to high population with the chronic conditions noted above. While the number of these FQHCs who were also geographically close to a college of pharmacy was much smaller, it is possible that the sites not close to colleges of pharmacy could find other partners (such as a local hospital or hospital foundation), and/or could seek a part-time rather than full-time clinical pharmacist.

- 2. Work with Primary Care Associations and other safety-net organization networks to encourage development of regional educational efforts and creating opportunities to share expertise with respect to implementing and sustaining clinical pharmacy services.** One of the barriers identified through the research conducted to prepare this report is the general lack of access to pharmacy-specific expertise in many safety-net providers, most significantly in FQHCs. Many organizations are not able to access or acquire this expertise individually due to cost restraints and geography, however, developing access through a Primary Care Association or an established network is one manner in which a broader array of organizations could have increased access to the expertise necessary to implement clinical pharmacy services. In addition, many FQHCs have not optimized the financial performance of their 340B medication program and centralizing expertise in improving this program among a group of health centers could generate new revenues that can be directed to supporting the delivery of clinical pharmacy services. It is known that a small number of networks (Mississippi and Iowa/Nebraska) have begun to evaluate centralizing pharmacy expertise at the network administration level and if these efforts are successful, federal

initiatives could disseminate this success and foster initiatives that encourage replication.

3. **Compare and disseminate improvement results between HRSA-sponsored disparities collaborative teams that do and do not include pharmacists.** If the results are favorable for teams with the pharmacists, HRSA could actively disseminate this information and encourage the inclusion of pharmacists on the teams.

Hundreds of FQHCs have participated in disease collaboratives that have worked to improve care for conditions including asthma, diabetes, depression, and cardiovascular disease—all conditions where the value of pharmacist intervention has been shown in the literature. However, to our knowledge, no study has directly compared results of disease management initiatives with and without pharmacists. If results are positive for the teams with pharmacists, HRSA would be in a position to directly link two important quality improvement efforts—efforts to advance clinical pharmacy services and disease management to reduce disparities.

To lay the groundwork to address financial barriers:

4. **Prioritize research to identify and then disseminate stronger evidence of cost benefits from clinical pharmacy services, which could encourage state Medicaid programs, other payers, and DSH hospitals to invest in these services.** If the “truth” is that clinical pharmacy services not only improve outcomes but also can stretch our health care dollars farther by producing better outcomes for the same dollars, or could even save money overall, then the failure to demonstrate that truth may be carrying a high human cost each month this information remains unknown. To date, such research with sound methodologies has been scarce and relatively small-scale (see Appendix A).

More research in existing programs within Medicaid and Medicare, and study of clinical pharmacy services in place in DSH hospitals, would contribute importantly to the ability to know the true benefit-cost implications of these services and then encourage spread of the services to capture these benefits. Also, increases in physician productivity were noted by several case study sites, and if this were quantified it could help identify cost benefits more clearly. Three specific types of research opportunities follow. However, since no single study could answer all the questions necessary to optimize clinical pharmacy services, consideration should also be given to developing a mechanism for supporting selected organizations to focus on clinical pharmacy services research over the longer term, perhaps as part of a focus on the larger topic of research on medication use system quality and safety. One existing model for this is HRSA’s Office of Rural Health Policy’s Rural Health Research Centers, which have vastly increased the knowledge base on rural health and health care.

- a) **Evaluate Second-Generation Medicaid Clinical Pharmacy Services.** Ultimately, improved financing from Medicaid in particular will be crucial to increasing clinical pharmacy services within the safety net. Medicaid service coverage and payment policies are traditionally determined by states through their state plans. States that want to pay for clinical pharmacy services usually submit a plan amendment to CMS for approval.

Evaluative information available now from some of the state Medicaid programs that currently pay for clinical pharmacy services is encouraging. In an interview for this study, Missouri reported a 2.5-to-1 return-on-investment.⁷ Box 2 provides more information about this program. North Carolina reported that the economic benefits outweighed investments in their nursing home-focused clinical pharmacy program by 13 to 1 (California HealthCare Foundation 2004). Iowa reported significant improvements in patient safety in the first year of their program, with no net increase in healthcare costs (Chrischilles et al. 2002). Minnesota also reports significant improvements in clinical outcomes, but does not yet have enough data to evaluate long-run cost impacts.

However, the research for this report did not find fully-implemented state payment policies for clinical pharmacy services that, if extended across many other states, would support much expansion of clinical pharmacy services among safety-net providers. State programs to date have tended to reach a relatively small proportion of the population with chronic diseases who the literature suggests might benefit from these services. (Each state program is summarized in Appendix E).

Some states, such as Missouri and Florida, are refining their efforts to broaden their availability and tie them more closely to patient safety and quality. Evaluations of those broader efforts, which may represent a second generation of Medicaid clinical pharmacy initiatives with more potential to support clinical pharmacy services in safety-net providers, will be important to build on the assessments completed to date. The specific plans for evaluation were unknown at the time of this writing, although these states were planning some type of assessment.

⁷ Verification of site self-reports was not included as a part of the background research for this report.

BOX 2: REPORTS FROM THE FIELD—STATE OF MISSOURI'S PHARMACY-ASSISTED COLLABORATIVE DISEASE MANAGEMENT PROGRAM

Background: Missouri's Pharmacy-Assisted Collaborative Disease Management Program began in 2002, focusing on asthma, diabetes, heart failure, depression, hyperlipidemia, COBD, HTN, and GERD. The state (through a contractor) enrolled physicians/pharmacist teams to create care plans for eligible patients, and allowed pharmacists to bill Medicaid for cognitive services. Specific pharmacies were approached based on claims data showing that a fee-for-service Medicaid patient with one of these conditions and very high expenses was using the pharmacy.

Authorization and Payment. The clinical pharmacy services were authorized through a state plan amendment, implemented as part of a larger effort to manage pharmacy benefits. Payment was \$50 for an initial visit and \$15 each for up to two follow-up visits.

Program Reach: In 2006, about 700 patients were reported to be served under the program.

Program Effectiveness: Relative to a control group, those beneficiaries reached under the program in 2006 had reduced hospitalizations relative to the prior year (33 percent increase vs. 45 percent in the control group), emergency department visits (3 percent increase vs. 28 percent in the control group), and drug-related problems (21 percent decrease vs. 129 percent increase) (Oestreich 2007).

Cost Savings: The state reports this program achieved a 2.5-to-1 return on investment, with increasing savings per person served during state fiscal years 2004-2006. Per beneficiary per month savings were estimated at \$428.76 in state fiscal year 2006 (Oestreich 2007).

Program Change: The state worked with area schools of pharmacy to develop a new program, to be implemented in 2008, that they expect to reach many more beneficiaries. The new program will use the state's advanced electronic health record system, in place since 2006, to identify and notify pharmacies about specific opportunities for improvement. Specifically, screens will be run with paid-claims data against clinical decision rules, looking for any of over 100 potential pharmacy-based interventions programmed into the system. Pharmacists who provide the intervention can bill \$50 for the intake visit, then \$15 for a follow-up intervention. Pharmacists will need to be certified as a disease management pharmacist in the state's system in order to bill for these services (an eight-hour program). The state's electronic health records system enables physicians to view all such services being provided to their patients.

- b) **Study cost-benefits for clinical pharmacy services with low-or-no eligibility criteria, at DSH hospitals with existing programs and/or through a Medicare demonstration simulating payment of MTM through Part B.** There is little understanding of what criteria are most appropriate for clinical pharmacy services to maximize clinical benefits population-wide and to bring a return-on-investment, or greater benefits with cost neutrality, to the health care system. Current eligibility requirements in Medicare Part D and

current criteria for state Medicaid programs are stringent relative to programs reported as successful from case study sites outlined in this report as well as those described in the literature. If eligibility criteria are restrictive, there are fewer patients to whom services can be provided and ultimately fewer encounters that can occur, making it challenging for providers to invest in the infrastructure to deliver the service. Studies cited in the literature review (Appendix A) and case study sites interviewed for this report generally use less stringent criteria than states or Medicare, if in fact they use specific criteria at all. Therefore, seeking a balance between criteria that appropriately define the population most in need or that represents the greatest return-on-investment, while ensuring a base that will support sustainability of clinical pharmacy services is an important issue.

An opportunity may exist to study economic benefits from existing clinical pharmacy services programs in DSH hospitals' outpatient departments (such as those we interviewed for the study) that currently either focus on a specific condition with no other criteria, or in primary care clinics that include no specific criteria other than a need for the services identified by the physician, the pharmacist, or the patient. Such a study would need to support the DSHs to track the clinical pharmacy services provided and would need to gain cooperation from a set of similar hospitals to serve as a comparison group. Such a study could provide a stronger business case model for DSHs to initiate these services. Depending on the study budget and information available from the sites, different levels of criteria could be simulated and effects projected, to help inform the question of what eligibility criteria, if any, are necessary to produce a positive return-on-investment.

Some safety-net sites and national stakeholders interviewed for this study viewed payment of MTM through Medicare Part B as a promising way to address financial barriers to clinical pharmacy services among safety-net providers, in part because it would establish a model for Medicare and other payers. Pharmacists would be recognized as providers and could bill directly without complicated program requirements and a third-party (the PDP) receiving some of the benefit. Therefore, a second option for testing the cost-benefits of these services using a model that could, if implemented nationally, result in widespread implementation of these services, would be a Medicare demonstration that simulated payment for these services under Part B.

- c) **Identify cost benefits to Medicare and Medicaid from existing Medicare MTM provided to dually-eligible beneficiaries or those who visit safety-net providers.** Although the current Medicare model of MTM is not likely to support widespread expansion of clinical pharmacy services among safety-net providers, Medicare's MTM still provides a learning laboratory from which useful lessons may be drawn. To produce information that would help fill the critical information gaps discussed above, a study could assess the net costs saved in Medicare across parts A, B, and D and Medicaid for dually-eligible

Medicare beneficiaries who receive MTM services, compared to those who do not, by type and frequency of MTM service received (in-person, telephone). Alternatively or in addition, the experience of Medicare beneficiaries who receive MTM services at safety-net providers could be compared to those who also visit safety-net providers but do not receive MTM services. Focusing on the dually-eligible population as a whole would produce results of greater interest to state Medicaid agencies, which, as discussed above, are a key audience to achieve changes in financing.

To address rural considerations:

5. **Explicitly consider the unique aspects of rural safety-net providers and of pharmacy service delivery in rural communities within the general options outlined in this report.** Many of the options described in this report, such as laying the groundwork to addressing financial barriers, encouraging safety-net provider/college of pharmacy linkages, and creating peer-to-peer networking and educational efforts have implications for expanding clinical pharmacy services in both urban and rural settings, however, it may require unique methods to make these efforts effective to these different audiences. Thus, when considering action on any of the options outlined in this report, the need for unique implementation strategies based on urban vs. rural audiences or based on safety-net provider type (FQHC/DSH hospital vs. RHC/CAH) should be considered.
6. **HRSA can encourage inclusion of clinical pharmacy services as part of supported telepharmacy projects through its Office of Health Information Technology, to increase the future ability of residents of remote areas to access clinical pharmacy services.** Adoption of telepharmacy applications is expanding in rural communities and, as described previously, is often being used primarily to support medication access/distribution within these communities. Federal programs that support telepharmacy initiatives, such as OHIT, could adopt a philosophy that clinical pharmacy services should be included in projects and programs that are associated with supporting effective medication use systems in safety-net organizations.
7. **HRSA should consider strengthening existing rural health programs (Area Health Education Centers, National Health Service Corps, and grant programs) to more explicitly support the integration of clinical pharmacy services into rural safety-net organizations.** There are several existing federal programs that support rural health care services that do not explicitly support development of clinical pharmacy services. For safety-net providers to recognize the importance of making high-quality clinical pharmacy services a core element of their programs, federal initiatives should seek to be aligned with sending this message directly and indirectly.

The HRSA-funded Area Health Education Centers (AHEC) program is designed to help address workforce supply issues in safety-net settings. Currently, only eight of the 49 AHEC programs nationally report training sites for pharmacy students in underserved areas. Strengthening the pharmacy component of this program by increasing the placement of pharmacy students in safety-net environments, including rural safety-net organizations, is one available tool to support a stronger future supply of pharmacists interested in working in rural communities. Some at the national stakeholders meeting also suggested that interprofessional development between physicians and pharmacists could be encouraged through the AHECs.

HRSA's National Health Service Corps (NHSC) loan repayment program, a key program to support supply of health professionals in underserved areas, does not now include pharmacists. However, a demonstration of the inclusion of pharmacists is underway, and results from the evaluation of that demonstration are due in spring 2008. If suggested by the evaluation, HRSA could begin to include pharmacists in the program as another mechanism to improve the availability of clinical pharmacists to both rural and urban safety-net organizations.

Additionally, opportunities to create educational efforts and promote federal initiatives related to clinical pharmacy services can be explored through the State Offices of Rural Health grant program. These offices, which provide an institutional framework that links small rural communities with State and Federal resources, can serve as an important outlet for communicating the value of clinical pharmacy services and connecting rural health care organizations with information and expertise to successfully expand the delivery of these services.

While these opportunities were highlighted in the background research for this report, it is notable that both were also highlighted by the 2006 National Advisory Committee on Rural Health and Human Services in their "Report to the Secretary." In addition, the committee also suggested that rural pharmacy services should be included as a focus for existing DHHS grant programs.

To take advantage of other opportunities:

8. Directly Encourage Safety-Net Provider/College of Pharmacy Linkages.

As many of the case study discussions and the prior Evaluation of the Clinical Pharmacy Demonstration Program suggest, the establishment of strong partnerships with colleges of pharmacy has been and remains a promising way to initiate or expand clinical pharmacy services in safety-net settings, both by providing financial stability for the programs and, in the longer term, by helping to provide a stable supply of pharmacists trained to provide clinical services in safety-net settings. HRSA may find opportunities to directly encourage safety-net provider/college of pharmacy linkages, for example, the agency may consider reshaping existing awards programs, such as the student chapter awards program sponsored by the Pharmacy Services Support Center, to

provide recognition and financial rewards to those pharmacy schools with the strongest relationships with safety-net providers.

9. **Continue to look for opportunities to raise expectations for clinical pharmacy services in safety-net providers that participate in HRSA-funded programs.** HRSA has already elevated its attention to safe medication use in safety-net providers, for example, by identifying and disseminating best practices. HRSA has also raised the expectation for the provision of clinical pharmacy services by requiring the provision of “pharmaceutical care” which includes medication therapy management, disease management and other clinical pharmacy services as a grant expectation for the newly released Comprehensive Pharmacy Services Supplemental Grant. The establishment of the Patient Safety and Clinical Pharmacy Collaborative led by HRSA’s Office of Pharmacy Affairs and the Quality Center will help to identify leading practices in the areas of clinical pharmacy, patient safety, and improved patient outcomes. Encouraging HRSA funded programs to enroll in the collaborative to implement identified best practices will help to raise the level of expectation of the incorporation of clinical pharmacy services into safety-net organizations. HRSA may identify other opportunities to raise expectations for clinical pharmacy services. For example, the National Quality Forum (NQF) has a Therapeutic Drug Management Quality Project underway that has drafted preferred practices for public comment (NQF 2008). HRSA may find opportunities to build on the NQF’s work through the routine evaluation of safety-net providers by its Office of Performance Review. Also, HRSA could begin to expect clinical pharmacy services to be built into FQHC new starts and expansions, where the anticipated patient mix includes a substantial volume of patients with chronic conditions.

B. OPTIONS FOR FOUNDATIONS, STATES, AND PROFESSIONAL AND PROVIDER ASSOCIATIONS

The preceding steps taken by the federal government in and of themselves will not be enough to result in the provision of a high level of clinical pharmacy services in safety-net settings. Other key players include foundations, state Medicaid agencies, and professional and provider associations.

1. Foundations could partner with the federal government to sponsor studies to help fill the information gap regarding whether there are cost savings from these services. Foundations could also provide start-up or ongoing financial assistance for clinical pharmacy services for interested safety-net providers who have used a financial planning tool and optimized existing sources of revenue.
2. State Medicaid agencies can decide to amend their state plans to pay for clinical pharmacy services, or include clinical pharmacy services as a part of a larger waiver application they may be planning. Similarly, Medicaid managed care

plans set their own payment policies and could choose to begin paying for these services.

3. National organizations concerned with Medicaid such as the National Academy for State Health Policy, National Association of State Medicaid Directors, National Governors' Association, and Center for Health Care Strategies Purchasing Institutes can help share experiences from the states that currently pay for clinical pharmacy services with other states, particularly as second-generation efforts such as those in Missouri and Florida become fully implemented.
4. With sponsorship, the American Association of Colleges of Pharmacy (AACP) could further its existing activities to create national networking opportunities between schools that have partnered with safety net organizations and those that have not. Strong academic-safety net partnerships can be more formally highlighted to increase the awareness of schools about the value to schools and communities engaged in this work. Furthermore, there may be ways in which existing AACP programming could be leveraged to support further expansion of these academic-practice partnerships.
5. The National Association of Chain Drug Stores (NACDS) can work with its members to further build on the contractual relationships established to date between FQHCs and other safety-net providers and chain drug stores. Almost 2,000 contractual relationships have been established between safety-net providers and independent and chain drug stores, with the assistance and encouragement of HRSA's Pharmacy Services Support Center. With encouragement from the NACDS, many more of these contracts could be established with chain drug stores, and they could be used to provide clinical pharmacy services as well as traditional pharmacy services.
6. The National Association of Community Health Centers (NACHC), National Association of Public Hospitals (NAPH), and other safety-net provider organizations can educate their members about the value of these services.
7. National pharmacy associations that currently provide awards to schools of pharmacy for program recognition or scholarships can include specific recognition or awards to schools with strong relationships with safety-net providers.
8. The state Boards of Pharmacy can increase their approval of telepharmacy networks in order to establish traditional and clinical pharmacy services for patients in remote locations.

C. CONCLUSION

In summary, clinical pharmacy services seem to hold great promise for improving the health of the many patients with chronic conditions who visit safety-net providers. The safety-net providers who have sustained these services are strongly committed to them because they find high value for patients and physicians. Further, some studies suggest clinical pharmacy services may stretch health care dollars further by producing better outcomes for the same cost, or may even save money for the health system overall. Federal actions in concert with efforts by private-sector organizations could improve the availability of clinical pharmacy services, through efforts to generate broader awareness of the benefits of these services found by the safety-net providers who do offer them, attention to opportunities to strengthen existing HRSA programs' emphasis on clinical pharmacy services, and encouragement of stronger linkages between schools of pharmacy and safety-net providers. Additional evidence of return on investment would be helpful to convince payers to extend payment for these services, and thus make these services financially sustainable across safety-net providers on a widespread basis.

REFERENCES

- Alliance for Aging Research. "When Medicine Hurts Instead of Helps." Washington, DC: The Alliance for Aging Research, 1998.
- California Healthcare Foundation. "Disease Management in Medicaid." 2004. Available at [www.chcf.org/documents/policy/DiseaseManagementInMedicaid2004.pdf]. Accessed December 10, 2007.
- Casey Michelle M., Ira Moscovice, and Gestur Davidson. "Pharmacist Staffing and the Use of Technology in Small Rural Hospitals: Implication for Medication Safety." Working Paper #1—Upper Midwest Rural Health Research Center. December 2005.
- Chiquette, Elaine, Mary G. Amato, and Henry I. Bussey. "Comparison of an Anticoagulation Clinic with Usual Medical Care: Anticoagulation Control, Patient Outcomes, and Health Care Costs." *Archives of Internal Medicine*, vol. 158, no. 5, August 10, 1998, pp. 1641-1647.
- Chrischilles, Elizabeth, Barry Carter, Margaret Voelker, David Scholz, Shari Chen-Hardee, Linda Rubenstein, Tae-Ryong Park, Brian Lund, Angela Kuehl, Gary Rosenthal, and Joseph Hanlon. "Iowa Medicaid Pharmaceutical Case Management Program: Report of the Program Evaluation." December 2002. Available at [www.iarx.org/Documents/PCM%20Final%20Report.pdf]. Accessed October 25, 2007.
- Epstein, Debbie. "Can Rural Pharmacy Survive?" *Drug Topics*, vol. 140, 1996, pp. 58-60 and 62-63.
- Felt-Lisk, Suzanne, Lindsay Harris, Meredith Lee, and Rebecca Nyman. "Evaluation of HRSA's Clinical Pharmacy Demonstration Projects." Final Report. Washington, DC: Mathematica Policy Research, Inc., November 2004.
- Fraher Erin P., Rebecca T. Slifkin, Laura Smith, Randy Randolph, Matthew Rudolf, and George M. Homes. "How Might the Medicare Prescription Drug, Improvement and Modernization Act of 2003 Affect the Financial Viability of Rural Pharmacies? An

- Analysis of Preimplementation Prescription Volume and Payment Sources in Rural and Urban Areas." *Journal of Rural Health*, vol. 21, no. 2, pp. 114-121, 2005.
- Gangeness, David. "Pharmaceutical Care for Rural Patients: Ominous Trends." *Journal of the American Pharmaceutical Association*, vol. NS37, 1997, pp. 62-65 and 84.
- Gengler, Deanna. "Modified Directly Observed Therapy (MDOT) in HIV Patients: An Observational Study in a Community Health Center." Report submitted to the Pharmaceutical Care Residency Program of the College of Pharmacy, University of Minnesota, August, 2005.
- Hogan, Elizabeth G., Sandra Leal, Marion Slack, and David Apgar. "Pharmacist-Led vs. Physician Diabetes Drug Management." *Hospital Pharmacy Europe*, Issue 26, July/August 2006, pp. 16-17.
- Johnson, Jeffrey, and J. Lyle Bootman. "Drug-Related Morbidity and Mortality: A Cost-of-Illness Model." *Archives of Internal Medicine*, vol. 155, 1995, pp. 1949-1956.
- Knapp, Katherine K, and James Cultice. "New Pharmacist Supply Projections: Lower Separation Rate, Increased Graduates Boost Supply Estimates." *Journal of the American Pharmacists Association*, vol. 47, no. 4, 2007, pp. 463-470.
- Knapp, Katherine K., Fred G. Paavola, Lucinda L. Maine, Bernard Sorofman, and Robert M. Politzer. "Availability of Primary Care Providers and Pharmacists in the United States." *Journal of the American Pharmaceutical Association*, vol. 39, 1999, pp. 127-135.
- Lai, L. Leanne, and Alan L. Sorkin. "Cost Benefit Analysis of Pharmaceutical Care in a Medicaid Population—From a Budgetary Perspective." *Journal of Managed Care Pharmacy*, vol. 4, 1998, pp. 303-308.
- Larson, E., K. Johnson, T. Norris, D. Lishner, R. Rosenblatt, and L. Hart. "State of the Health Workforce in Rural America Profiles and Comparisons." Seattle, WA: WWAMI Rural Health Research Center, 2003, pp. 23-45.
- Sandra Leal, Jon Glover, Richard Herrier, and Anthony Felix. "Improving Quality of Care in Diabetes Through a Comprehensive Pharmacist-Based Disease Management Program." *Diabetes Care*, vol. 27, no. 12, December 2004, pp. 2983-2984
- National Advisory Committee on Rural Health and Human Services. "The 2006 Report to the Secretary: Rural Health and Human Service Issues." January 2006. Available at [<http://ruralcommittee.hrsa.gov>].
- Oestrich, George L. "MO HealthNet MTM." Presentation to the Medication Therapy Management Services in Community Pharmacy (APhA) Conference, September 2007.

Salary.com Online. Available at http://swz.salary.com/salarywizard/layouthtmls/swzl_compresult_national_HC07000012.html. Accessed 1/3/08.

Shane-McWhorter, Laura, and Gary M. Oderda. "Providing Diabetes Education and Care to Underserved Patients in a Collaborative Practice at a Utah Community Health Center." *Pharmacotherapy*, vol. 25, no. 1, January 2005, pp. 96-109.

Skoglund, Krissa J. "Rheumatoid Arthritis Management Program." Report submitted to the Pharmaceutical Care Residency Program of the College of Pharmacy, University of Minnesota, June 2005.

Traynor, Andrew P., and Todd D. Sorensen. "Student Pharmacist Perspectives of Rural Pharmacy Practice." *Journal of the American Pharmaceutical Association*, vol. 45, 2005, pp. 694-699.

University of Minnesota Medical School. "Rural Physician Associate Program Summary." Minneapolis, MN: University of Minnesota, 2004-2005.

Xiao, Hong, Bernard Sorofman, and Henri Manasse. "The Association Between Pharmacy Closures and Prescription Drug Use: A Retrospective Analysis of Medicaid Prescription Claims in Iowa." *American Journal of Managed Care*, 2000(a), vol. 6, pp. 366-372.

Xiao, Hong, Bernard Sorofman, and Henri Manasse. "Impact of Pharmacy Closures on Patient Use of Prescription Drugs." *Journal of Social and Administrative Pharmacy*, vol. 17, no. 1, 2000(b), pp. 25-33.

APPENDIX A

LITERATURE REVIEW

A literature search was conducted to identify research on the clinical and economic effects of clinical pharmacy services that took place in ambulatory care settings and could be potentially appropriate for safety-net health centers as well as for hospitals (e.g., articles on effects of clinical pharmacy services on transplant patients' recovery were excluded). Taken together, the literature is highly positive, suggesting clinical pharmacy services can help to improve clinical outcomes for several common chronic conditions where medication is an integral part of that treatment. The literature regarding cost savings is thin, however existing studies find clinical pharmacy services are either cost neutral or result in cost savings when the full spectrum of patient care is included in the cost calculation.

A. METHOD

The literature review used the electronic databases OVID and EBSCO Host. Relevant search terms and phrases included: "clinical pharmacy" and "comparative study;" "clinical pharmacy;" "clinical pharmacist;" "medication therapy management;" "diabetes" and "pharmacy;" "diabetes" and "pharmacist;" "asthma" and "pharmacy;" and "asthma" and "pharmacist." The various searches yielded more than 3,000 article titles. Additional studies were included at the suggestion of professionals in the field as well as a Mathematica senior staff member with experience in the field. Those studies with comparison groups—a small fraction of the total—were reviewed more carefully. The results presented below represent a qualitative summary of the literature, focused on studies with patient populations of reasonable size, having comparison groups, and based on data from developed countries—characteristics that increase the likelihood that the study results could be replicated in the U.S. and that the results are attributable to the intervention.⁸ Many other positive reports from the field have been published that lack control groups or include only small samples, so

⁸ Strict sample size criteria were not set, but no studies are presented here with fewer than 125 patients, and all but three studies analyze intervention groups of sample sizes greater than 100. (The three studies with intervention group sample sizes less than 100 are: Finley et al. 2002; Finley et al. 2003; and Scott et al. 2006. The intervention group sample sizes in these studies are 91, 75, and 76, respectively.)

they are not mentioned here. Also of note, studies with control groups but with small samples (for example those with 70 or fewer in the intervention group) tend to be more mixed in their findings relative to the studies featured here, with a substantial number of them reporting insignificant results, probably because they were not designed to be large enough to have realistic potential for showing effect.

B. SUMMARY OF CLINICAL OUTCOMES OF CLINICAL PHARMACY SERVICES

Clinical pharmacy services have been found to have positive clinical effects across a range of chronic conditions and in a variety of health care settings. Most studies found involved pharmacists providing care to patient populations with specific chronic conditions. For this reason, and because pharmacists' ability to improve outcomes may vary by condition, clinical outcomes are provided below by condition. For each condition, we first remind the reader of the significance of the problem that the pharmacist intervention may help solve.

Diabetes. Better glycosylated hemoglobin (HbA1c) control in people with diabetes is associated with lower risk of death and cardiovascular complications. One major study found that among patients with type 2 diabetes, each 1 percent reduction in updated HbA1c lowered the risk of death by 21 percent, heart attack by 14 percent, and "microvascular complications" by 37 percent (Stratton et al. 2000). This review found two relatively strong studies in community pharmacies in Australia and one in a university-affiliated clinic in North Carolina that suggest that pharmacists can play a significant role in reducing HbA1c levels and blood pressure control among patients with diabetes (Krass et al. 2007; Clifford et al. 2005; Rothman et al. 2005), as well as several studies with positive results in community health centers (Scott et al. 2006; Hogan et al. 2006; Shane-McWhorter and Oderda 2005).

In the two Australian studies, pharmacists' activities included education on disease, medications, and lifestyle; identifying and planning for resolution of medication-related problem; and regular follow-up with the patient via phone or in-person meetings for monitoring and adherence support over a 6- or 12-month period. In both of these studies, the pharmacist could not adjust medication directly, but advised patients to follow up with their physician when adjustments were found to be needed. The North Carolina study included similar activities provided over a 12-month period, except that the pharmacists could initiate and increase use of blood pressure-, cholesterol-, and glucose-lowering medications in keeping with evidence-based treatment algorithms with input from the practice physicians. Information was shared with each patient's primary care practitioner. Two of the three pharmacists delivering the services were certified diabetes educators. Notably, two literature reviews with slightly different foci than this one found that pharmacists working under collaborative practice agreements who could make direct

medication changes had significantly greater effects on HbA1c than those without such privileges (Wubben and Vivian 2007; Shojania et al. 2006).⁹

The three published studies that feature clinical pharmacy services at federally qualified health centers (FQHCs) each demonstrated improved HbA1c control and improved low-density lipoprotein cholesterol (LDL) relative to a comparison group (Scott et al. 2006; Hogan et al. 2006; Shane-McWhorter and Oderda 2005). Two studies also showed improved receipt of some guideline-recommended preventive services, such as flu vaccine and annual retinal exam (Scott et al. 2006; Shane-McWhorter and Oderda 2005). In addition, one study showed improved systolic blood pressure and total cholesterol over a nine-month period, improvements in use of daily aspirin for cardiovascular risk prevention, and improvements in diabetes quality of life scores, including health and worry about disease, based on a patient-reported survey (Scott et al. 2006).

The interventions in all three FQHCs included education of patients about the condition beyond just the medication. In one FQHC (Shane-McWhorter and Oderda 2005), the pharmacist was also a certified diabetes educator who provided extensive education in addition to medical-chart review, recommended changes in medication therapy to the provider, and reminded patients about preventive services due. In another FQHC (Scott et al. 2006), the intervention included biweekly appointments with the pharmacist, followed by recommendations for changes in medication therapy and monitoring to the patient and his or her physician as appropriate, and two-hour group educational sessions with the pharmacist, a dietician, and a nurse.

A study of more than a dozen other networks of FQHCs and schools of pharmacy also showed that patients who are reached and retained in diabetes-focused disease management efforts led by pharmacists tend to show significantly reduced HbA1c levels, with average blood pressure and LDL also significantly improved (Felt-Lisk et al. 2004). However, this and many other case studies reported in the literature do not have strong comparison or control groups; when those groups are included, researchers usually find some improvement in the comparison or control groups as well.

Dyslipidemia. Dyslipidemia, which can involve elevated levels of total and low-density lipoprotein cholesterol (LDL) and reduced levels of high-density lipoprotein cholesterol (HDL), increases the risk of heart disease. The treatment of this condition has been shown to reduce morbidity and mortality related to cardiovascular disease (Shepherd et al. 2002; Scandinavian Simvastatin Survival Study Group 1994). The Third Report of the National Cholesterol Education Program Expert Panel recommends goals of treatment for primary prevention of LDL <160 mg/dL or <130 mg/dL, depending on the number of risk factors present; the optimal goal of secondary prevention therapy is LDL <100 mg/dL (National Cholesterol Education Program, 2007).

⁹ The Wubben and Vivian review was more inclusive of studies with small sample sizes, and the Shojania et al. review included many types of quality improvement efforts for diabetes and did not compare efforts that used pharmacists to other types of efforts.

A comprehensive review of the literature in 2005 found that when pharmacists are involved in treating dyslipidemia, the overall effect is positive: LDL and total cholesterol levels are reduced, HDL levels are increased, and more patients achieve the goals specified by the National Cholesterol Education Program (Cross and Franks 2005). Pharmacist involvement usually consisted of ordering or performing lab tests, changing or recommending changes to drug therapy, providing education about the condition, and following up with patients over periods of several months or more. The authors conclude that clinic-based programs appear to be more successful than community pharmacy-based programs, although studies in both settings provide evidence of positive effect.

Hypertension. High blood pressure significantly increases the risk of heart attack, heart failure, and stroke. Appropriate pharmaceutical therapy has been shown to prevent one or more forms of cardiovascular disease (ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group 2002). One study with a relatively strong study design, albeit limited to patients in a single health plan, focused on patients with mild to moderate essential hypertension. That study found that the pharmacist-managed hypertension group experienced significant decreases in both systolic and diastolic blood pressure relative to the control group over the six-month study period (Okamoto and Nakahiro 2001). The pharmacist determined the most appropriate antihypertensive regimen for the patient, ordered laboratory tests as needed, and provided education on non-pharmacologic ways to control blood pressure.

Hypertension is often a co-morbidity with diabetes. Studies of pharmacist interventions in diabetes care in safety-net settings have found that these interventions can also result in blood pressure reductions (Felt-Lisk et al. 2004; Shane-McWhorter and Oderda 2005).

Asthma. Asthma accounts for 1.8 million emergency department visits, over 400,000 hospitalizations, and 3,816 deaths annually, with morbidity and mortality worse among low-income populations and ethnic minorities, particularly blacks and Puerto Ricans (CDC National Center for Health Statistics 2007; Akinbami 2007; Self et al. 2005).

Evidence from two well-designed studies abroad (Canada and Australia) suggests that pharmacists with training in asthma pharmaceutical care can have a positive impact on asthma control. The Canadian intervention included teaching patients asthma self-management as outlined in the Health Outcome Pharmacies Asthma Care Module; educating them about the disease, medications being used, and proper use of a peak flow meter; and helping them develop an asthma action plan, with follow-up for a year (McLean et al. 2003). At study's end, the intervention group had significantly better outcomes compared to the usual-care group, including higher peak expiratory flow rates, greater improvement in symptom scores, and fewer medical visits. Under the Australian study, pharmacists in 50 pharmacies implemented an ongoing cycle of assessment, goal-setting, monitoring, and review over a six-month period. Results showed that intervention patients were much more likely than the control group to improve from "severe" to "not severe," and that they were more likely to adhere to preventer medications (Armour et al. 2007).

One U.S.-based study of a pharmaceutical program delivered by community pharmacists reports more mixed findings. This study, which included education, monitoring, and follow-up to patients with chronic obstructive pulmonary disease (COPD) and asthma, reported approximately similar improvements in peak flow rates compared with a control group consisting of patients receiving only monthly monitoring of peak flow rates (Weinberger et al. 2002).

Anticoagulation. Anticoagulation treatment is a high-risk therapy and requires careful monitoring to reduce the risks of subsequent adverse drug events, bleeding episodes, and thrombolytic events associated with anticoagulation, so much so that reducing harm from anticoagulation therapy was named as a 2008 patient safety goal by the Joint Commission on Accreditation of Healthcare Organizations. According to a relatively strong study of a pharmacist intervention to improve anticoagulation therapy, which was conducted in a university health care system with a high proportion of indigent patients, patients who attended the pharmacist-run anticoagulation clinic experienced lower rates of significant bleeding, lower rates of major fatal bleeding, fewer thrombolytic events, lower annual rates of warfarin sodium-related hospitalizations, and lower rates of warfarin-unrelated emergency department visits (Chiquette et al. 1998). The anticoagulation clinic was located in the university's general medicine clinics, and most patients were seen by pharmacy students or residents, with oversight from faculty physicians. The pharmacists conducted an initial patient risk assessment, assessed the antithrombotic regimen and adjusted it as indicated, and provided intensive patient education. Follow-up visits occurred normally at intervals of four weeks or less. Another study in a health plan found that even a telephone-based pharmacy anticoagulation service was associated with positive outcomes compared with a control group (Witt et al. 2005).

Depression. The World Health Organization projects that by 2030 the three leading causes of burden of disease will be HIV/AIDS, depression, and ischemic heart disease (Mathers and Loncar 2006). Diagnosis of depression and subsequent treatment is integral to curbing the burden of the condition, as it has been estimated that less than half of those with symptoms of probable depression receive treatment (Young et al. 2001). Depression is one of five national priorities of the Institute of Medicine for quality improvement (Institute of Medicine Committee on Quality of Health Care 2001), so there are efforts to improve diagnosis and treatment of depression through primary care settings, as many access health care via primary care providers (Croghan et al. 2006). Related to the burden associated with depression are the high rates of medication non-adherence among depressed individuals, which is a major factor in relapse and recurrence of the condition (Melfi et al. 1998).

Existing evidence is encouraging that clinical pharmacists may play a positive role in facilitating medication adherence among individuals diagnosed with depression. In two studies at Kaiser Permanente medical centers, patients in the study groups exhibited significantly higher drug adherence rates than those of control group patients (Finley et al. 2002; Finley et al. 2003). Similarly, a pharmacist intervention for depressed patients served by nine primary care practices in Massachusetts, including a community health center, significantly increased antidepressant use rates among study group patients, and the antidepressant use rates of the intervention patients were higher than those of a control

group (Adler et al. 2003). In all cases the pharmacist's intervention included a relatively intensive intake interview, educating the patient about depression and anti-depressants, and repeated contacts to monitor and follow-up with the patient over a period of 24 weeks or six months. In one of the studies at Kaiser Permanente, the pharmacist worked under a protocol allowing him/her to titrate the medications, whereas in the other two all changes were recommended to the patient's primary care physician.

C. SUMMARY OF ECONOMIC BENEFITS OF CLINICAL PHARMACY SERVICES

While most of the published research on the economic benefits of clinical pharmacy services lacks strong study designs, existing studies point in a positive direction, finding cost savings or at least cost neutrality along with better outcomes from clinical pharmacy services (Shumock et al. 2003).

One highly relevant study examined the economic effects of pharmaceutical care services provided by two clinical pharmacists at four hospital-based outpatient primary care clinics serving Medicaid beneficiaries in inner-city Baltimore, MD, compared to a control group of Medicaid beneficiaries receiving usual medical care (Lai and Sorokin 1998). Schumock and colleagues (2003) estimated that the cost-benefit ratio of the program in its first year was 2.06:1, taking into account program input costs as well as total prescription costs and costs to the Medicaid program, which were significantly less in the study group. Extrapolating these results to all state Medicaid recipients, Lai and Sorokin estimated that the state Medicaid program could save \$22 million during the following fiscal year. Unlike the studies described above, this program was not targeted to a specific disease. Pharmacists screened all patients' Medicaid eligibility, reviewed their medical charts, and identified potential drug-related problems. They were permitted to recommend changes in therapy to the physicians and/or request interviews while the patients were being seen by their physicians. They also performed follow-up pharmacotherapy consultations with and clinical outcomes assessments (such as hypertension, asthma, and anticoagulation) of the patients, if necessary.

When it comes to disease-specific approaches, Chiquette and colleagues report cost savings from an **anticoagulation** clinic run by a clinical pharmacist of \$162,058 per 100 patients annually, due to reduced hospitalizations and emergency department visits (Chiquette et al. 1998). A study taking place at several Veterans Affairs Medical Centers displayed improved clinical outcomes at no additional cost among older patients with **dyslipidemia** treated by ambulatory care clinical pharmacists versus a comparison group (Ellis et al. 2000). In a study comparing pharmacist-managed **hypertension** care to usual care over six months, Okamoto and Nakahiro (2001) found that total costs were not different but that the pharmacist-managed clinic group was more cost-effective, that is, better outcomes were achieved for each dollar spent. Specifically, the cost of decreasing diastolic blood pressure 1 mm Hg was \$48 for the pharmacist-managed clinic group versus \$151 for the physician-managed clinic. Although the number of emergency room visits was lower, Okamoto and Nakahiro found that the number of clinic visits was higher in the pharmacist-managed group, and there was no difference between the groups in hospitalizations or average number of drugs taken.

Since utilization drives cost, studies that examine utilization changes due to clinical pharmacy services are also of interest when reviewing evidence for cost effects. A nine-month pharmacist intervention for patients with **heart failure** served by a university-affiliated, inner-city, ambulatory care practice improved medication adherence and reduced emergency room visits and hospital admissions among an intervention group of patients, compared to a control group (Murray et al. 2007).¹⁰ McLean and colleagues found that, compared to a control group, a group of **asthma** patients receiving care from specially trained community pharmacists in British Columbia demonstrated significant improvements in symptom scores while experiencing significant decreases in both emergency room and medical visits (McLean et al. 2003). On the other hand, a study of patients with **diabetes** in a university-affiliated clinic found no difference between intervention and control groups in utilization of emergency or hospital services (Rothman et al. 2005).

¹⁰ Although the study also estimated costs saved of \$2960 per patient, the difference between intervention and control group costs was not significant due to large variability in costs.

REFERENCES

- Adler, David A., Kathleen M. Bungay, Ira B. Wilson, Yu Pei, Stacey Supran, Emily Peckham, Diane J. Cynn, and William H. Rogers. "The Impact of a Pharmacist Intervention on 6-Month Outcomes in Depressed Primary Care Patients." *General Hospital Psychiatry*, vol. 26, 2004, pp. 199-209.
- Akinbami, Lara. "Asthma Prevalence, Health Care Use and Mortality: United States, 2003–05." CDC National Center for Health Statistics. Accessed October 22, 2007. Available at: <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/ashtma03-05/asthma03-05.htm>.
- ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. "Major Outcomes in High-Risk Hypertensive Patients Randomized to Angiotensin-Converting Enzyme Inhibitor or Calcium Channel Blocker vs. Diuretic: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT)." *Journal of the American Medical Association*, vol. 288, no. 23, December 18, 2002, pp. 2981–2997.
- Armour, Carol, Synthia Bosnic-Anticevich, Martha Brilliant, Debbie Burton, Lynne Emmerton, Ines Krass, Bandana Saini, Lorraine Smith, and Kay Stewart. "Pharmacy Asthma Care Program (PACP) Improves Outcomes for Patients in the Community." *Thorax*, vol. 62, no. 6, June 2007, pp. 496–592.
- Armour, Carol L., Susan J. Taylor, Fleur Hourihan, Carlene Smith, and Ines Krass. "Implementation and Evaluation of Australian Pharmacists' Diabetes Care Services." *Journal of the American Pharmacists Association*, vol. 44, no. 4, July-August 2004, pp. 455-466.
- Centers for Disease Control and Prevention National Center for Health Statistics. "Fast Stats A to Z: Asthma." Accessed October 22, 2007. Available at: <http://www.cdc.gov/nchs/fastats/asthma.htm>.
- Chiquette, Elaine, Mary G. Amato, and Henry I. Bussey. "Comparison of an Anticoagulation Clinic with Usual Medical Care: Anticoagulation Control, Patient Outcomes, and Health Care Costs." *Archives of Internal Medicine*, vol. 158, no. 5, August 10, 1998, pp. 1641–1647.
- Choe, H.M., S. Mitrovich, D. Dubay, R.A. Hayward, S.L. Krein, and S. Vijan. "Proactive Case Management of High-Risk Patients with Type 2 Diabetes Mellitus by a Clinical Pharmacist: A Randomized Controlled Trial." *American Journal of Managed Care*, vol. 11, no. 4, April 2005, pp. 253-260.
- Clifford, Rhonda M., Wendy A. Davis, Kevin T. Batty, and Timothy M.E. Davis. "Effect of a Pharmaceutical Care Program on Vascular Risk Factors in Type 2 Diabetes: The Fremantle Diabetes Study." *Diabetes Care*, vol. 28, no. 4, April 2005, pp. 771-776.

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- Clifford, Rhonda M., Kevin T. Batty, Timothy M.E. Davis, Wendy Davis, Gary Stein, Graeme Stewart, and Richard Plumridge. "A Randomised Controlled Trial of a Pharmaceutical Care Programme in High-Risk Diabetic Patients in an Outpatient Clinic." *International Journal of Pharmacy Practice*, vol. 10, no. 2, 2002, pp. 85-89.
- Croghan, Thomas W., Michael Schoenbaum, Cathy D. Sherbourne, and Paul Koegel. "A Framework to Improve the Quality of Treatment for Depression in Primary Care." *Psychiatric Services*, vol. 57, no. 5, May 2006, pp. 623-630.
- Cross, L. Brian, and Andrea S. Franks. "Clinical Outcomes Associated with Pharmacist Involvement in Patients with Dyslipidemia: A Review." *Disease Management & Health Outcomes*, vol. 13, no. 1, February 2005, pp. 31-42.
- Davidson, Mayer B., Vicki J. Karlan, and Terry L. Hair. "Effect of a Pharmacist-Managed Diabetes Care Program in a Free Medical Clinic." *American Journal of Medical Quality*, vol. 15, no. 4, July/August 2000, pp. 137-142.
- Ellis, Samuel L., Barry L. Carter, Daniel C. Malone, Sarah J. Billups, Gary J. Okano, Robert J. Valuck, Debra J. Barnette, Charles D. Sintek, Douglas Covey, Barbara Mason, Sandra Jue, Jannet Carmichael, Kelly Guthrie, Robert Dombrowski, Douglas R. Geraets, and Mary Amato. "Clinical and Economic Impact of Ambulatory Care Clinical Pharmacists in management of Dyslipidemia in Older Adults: The IMPROVE Study." *Pharmacotherapy*, vol. 20, no. 12, 2000, pp. 1508-1516.
- Felt-Lisk, Suzanne, Lindsay Harris, Meredith Lee, and Rebecca Nyman. "Evaluation of HRSA's Clinical Pharmacy Demonstration Projects: Final Report." Washington, DC: Mathematica Policy Research, Inc., November 2004.
- Finley, Patrick R., Heidi R. Rens, Joan T. Pont, Susan L. Gess, Clifton Louie, Scott A. Bull, and Lisa A. Bero. "Impact of a Collaborative Pharmacy Practice Model on the Treatment of Depression in Primary Care." *American Journal of Health-System Pharmacy*, vol. 59, August 15, 2002, pp. 1518-1526.
- Finley, Patrick R., Heidi R. Rens, Joan T. Pont, Susan L. Gess, Clifton Louie, Scott A. Bull, Janelle Y. Lee, and Lisa A. Bero. "Impact of a Collaborative Care Model on Depression in a Primary Care Setting: A Randomized, Controlled Trial." *Pharmacotherapy*, vol. 23, no. 9, 2003, pp. 1175-1185.
- Gong, Cindy, Noelle K. Hasson, and Bert L. Lum. "Impact of a Diabetes Disease Management Clinic on the Total Glycosylated Hemoglobin of Patients with Type 2 Diabetes Mellitus." *Journal of Managed Care Pharmacy*, vol. 5, no. 6, 1999, pp. 511-515.
- Hogan, Elizabeth G., Sandra Leal, Marion Slack, and David Apgar. "Pharmacist-led vs. Physician Diabetes Drug Management." *Hospital Pharmacy Europe*, Issue 26, July/August 2006, pp. 16-17.

- Institute of Medicine Committee on Quality of Health Care in America. *Crossing the Quality Chasm*. Washington, DC: National Academy Press, 2001.
- Jaber, L.A., H. Halapy, M. Fernet, S. Tummalapalli, and H. Diwakaran. "Evaluation of a Pharmaceutical Care Model on Diabetes Management." *The Annals of Pharmacotherapy*, vol. 30, no. 3, March 1996, pp. 238-243.
- Krass, I., C.L. Armour, B. Mitchell, M. Brilliant, R. Dienaar, J. Hughes, P. Lau, G. Peterson, K. Stewart, S. Taylor, and J. Wilkinson. "The Pharmacy Diabetes Care Program: Assessment of a Community Pharmacy Diabetes Service Model in Australia." *Diabetic Medicine*, vol. 24, 2007, pp. 677-683.
- Krass, Ines, Susan J. Taylor, Adrian D. McInman, and Carol L. Armour. "The Pharmacist's Role in Continuity of Care in Type 2 Diabetes: An Evaluation of a Model." *Journal of Pharmacy Technology*, vol. 22, no. 1, 2006, pp. 3-8.
- Lai, L. Leanne, and Alan L. Sorkin. "Cost Benefit Analysis of Pharmaceutical Care in a Medicaid Population – From a Budgetary Perspective." *Journal of Managed Care Pharmacy*, vol. 4, 1998, pp. 303-308.
- Mathers, Colin D., and Dejan Loncar. "Projections of Global Mortality and Burden of Disease from 2002 to 2030." *PLoS Medicine*, vol. 3, issue 11, November 2006, pp. 2011-2030.
- McLean, William, Jane Gillis, and Ron Waller. "The BC Community Pharmacy Asthma Study: A Study of Clinical, Economic and Holistic Outcomes Influenced by an Asthma Care Protocol Provided by Specially Trained Community Pharmacists in British Columbia." *Canadian Respiratory Journal*, vol. 10, no. 4, May-June 2003, pp. 195-202.
- Melfi, Catherine A., Anita J. Chawla, Thomas W. Croghan, Mark P. Hanna, Sean Kennedy, and Kate Sredl. "The Effects of Adherence to Antidepressant Treatment Guidelines on Relapse and Recurrence of Depression." *Archives of General Psychiatry*, vol. 55, December 1998, pp. 1128-1132.
- Murray, Michael D., James Young, Shawn Hoke, Wanzhu Tu, Michael Weiner, Daniel Morrow, Kevin T. Stroupe, Jingwei Wu, Daniel Clark, Faye Smith, Irmina Gradus-Pizlo, Morris Weinberger, and Craig Brater. "Pharmacist Intervention to Improve Medication Adherence in Heart Failure, A Randomized Trial." *Annals of Internal Medicine*, vol. 146, no. 10, May 15, 2007, pp. 714-725.
- National Cholesterol Education Program. "Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III): Executive Summary." Accessed October 10, 2007. Available at: <http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3xsum.pdf>.

- Odegard, Peggy S., Alvin Goo, Jeff Hummel, Kristal L. Williams, and Shelly L. Gray. "Caring for Poorly Controlled Diabetes Mellitus: A Randomized Pharmacist Intervention." *The Annals of Pharmacotherapy*, vol. 39, no. 3, March 2005, pp. 433-440.
- Okamoto, Mark P., and Randy K. Nakahiro. "Pharmacoeconomic Evaluation of a Pharmacist-Managed Hypertension Clinic." *Pharmacotherapy*, vol. 21, no. 11, 2001, pp. 1337-1344.
- Plumridge, Richard J., and Richard E. Wojnar-Horton. "A Review of Pharmacoeconomics of Pharmaceutical Care." *Pharmacoeconomics*, vol. 14, no. 2, August 1998, pp. 175-189.
- Rothman, Russell L., Robb Malone, Betsy Bryant, Ayumi K. Shintani, Britton Crigler, Darren A. Dewalt, Robert S. Dittus, Morris Weinberger, and Michael P. Pignone. "A Randomized Trial of a Primary Care-Based Disease Management Program to Improve Cardiovascular Risk Factors and Glycated Hemoglobin Levels in Patients with Diabetes." *The American Journal of Medicine*, vol. 188, no. 3, March 2005, pp. 276-284.
- Scandinavian Simvastatin Survival Study Group. "Randomised Trial of Cholesterol Lowering in 4,444 Patients with Coronary Heart Disease: The Scandinavian Simvastatin Survival Study (4S)." *Lancet*, vol. 344, no. 8934, November 19, 1994, pp. 1383-1389.
- Schumock, Glen T., Melissa G. Butler, Patrick D. Meek, Lee C. Vermeulen, Bhakti V. Arondekar, and Jerry L. Bauman. "Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996-2000." *Pharmacotherapy*, vol. 23, no. 1, 2003, pp. 113-132.
- Scott, David M., Steven T. Boyd, Michelle Stephan, Sam C. Augustine, and Thomas P. Reardon. "Outcomes of Pharmacist-Managed Diabetes Care Services in a Community Health Center." *American Journal of Health-System Pharmacy*, vol. 63, no. 21, November 1, 2006, pp. 2116-2122.
- Self, Timothy, Cary Chrisman, Darius Mason, and Mark Rumbak. "Reducing Emergency Department Visits and Hospitalizations in African American and Hispanic Patients with Asthma: A 15-Year Review." *Journal of Asthma*, vol. 42, no. 10, December 2005, pp. 807-812.
- Shane-McWhorter, Laura, and Gary M. Oderda. "Providing Diabetes Education and Care to Underserved Patients in a Collaborative Practice at a Utah Community Health Center." *Pharmacotherapy*, vol. 25, no. 1, January 2005, pp. 96-109.
- Shepherd, James, Gerard J. Blauw, Michael B. Murphy, Edward L.E.M. Bollen, Brendan M. Buckley, Stuart M. Cobbe, Ian Ford, Allan Gaw, Michael Hyland, J. Wouter Jukema, Adriaan M. Kamper, Peter W. Macfarlane, A. Edo Meinders, John Norrie, Chris J. Packard, Ivan J. Perry, David J. Scott, Brian J. Sweeney, Cillian Twomey, and Rudi G.J. Westendorp. "Pravastatin in Elderly Individuals at Risk of Vascular Disease (PROSPER): A Randomised Controlled Trial." *Lancet*, vol. 360, no. 9346, November 23, 2002, pp. 1623-1630.

- Shojania, Kaveh G., Sumant R. Ranji, Kathryn M. McDonald, Jeremy M. Grimshaw, Vandana Sundaram, Robert J. Rushakoff, and Douglas K. Owens. "Effects of Quality Improvement Strategies for Type 2 Diabetes on Glycemic Control." *Journal of the American Medical Association*, vol. 296, no. 4, July 26, 2006, pp. 427-440.
- Stratton, Irene M., Amanda I. Adler, H. Andrew W. Neil, David R. Matthews, Susan E. Manley, Carole A. Cull, David Hadden, Robert C. Turner, and Rury R. Holman. "Association of Glycaemia with Macrovascular and Microvascular Complications of Type 2 Diabetes (UKPDS 35): Prospective Observational Study." *British Medical Journal*, vol. 321, no. 7258, August 12, 2000, pp. 405-412.
- Weinberger, Morris, Michael D. Murray, David G. Marrero, Nancy Brewer, Michael Lykens, Lisa E. Harris, Roopa Seshadri, Helena Caffrey, J. Franklin Roesner, Faye Smith, A. Jeffrey Newell, Joyce C. Collins, Clement J. McDonald, and William M. Tierney. "Effectiveness of Pharmacist Care for Patients with Reactive Airways Disease: A Randomized Controlled Trial." *Journal of the American Medical Association*, vol. 288, no. 13, October 2, 2002, pp. 1594-1602.
- Witt, Daniel M., Melanie A. Sadler, Roberta L. Shanahan, Georgann Mazzoli, and Donald J. Tillman. "Effect of Centralized Clinical Pharmacy Anticoagulation Service on the Outcomes of Anticoagulation." *Chest*, vol. 127, no. 5, May 2005, pp. 1515-1522.
- Wubben, Deborah P., and Eva M. Vivian. "Effects of Outpatient Interventions by Pharmacists on Patient Outcomes in Adults with Diabetes Mellitus." Abstract in: *Diabetes*, vol. 56, supplement 1, June 2007, p. A316.
- Young, AS, R. Klap, C.D. Sherbourne, and K.B. Wells. "The Quality of Care for Depressive and Anxiety Disorders in the United States." *Archives of General Psychiatry*, vol. 58, no. 1, January 2001, pp. 55-61.

APPENDIX B

DEFINITIONS OF THE TYPES OF SAFETY- NET PROVIDERS DISCUSSED IN THIS REPORT

FEDERALLY QUALIFIED HEALTH CENTERS

FQHCs are safety-net providers such as community health centers, public housing centers, outpatient health programs funded by the Indian Health Service, and programs serving migrants and the homeless. FQHCs receive cost-based reimbursement from Medicare and state Medicaid programs, and grant funding from HRSA. The main purpose of the special payment and grants provided to FQHCs is to enhance the provision of primary care services in underserved urban and rural communities. (FQHC Look-Alikes do not receive HRSA grants but do receive cost-based reimbursement from Medicare and Medicaid—data from these organizations was not included in the dataset used for the analysis provided in this report, because it is not available.) Additional information on FQHCs is available at :

<http://bphc.hrsa.gov/about/>

<http://www.cms.hhs.gov/MLNProducts/downloads/fqhcfactsheet.pdf>

<http://www.nachc.com/research/Files/IntroHealthCenters8.06.pdf>

AIDS DRUG ASSISTANCE PROGRAM SITES

The AIDS Drug Assistance Program (ADAP) provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients. Amendments to the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in October 2000 added language allowing ADAP funds to be used for services that enhance access to, adherence to, and monitoring of drug treatments. The program is funded through Title II of the CARE Act, which provides grants to States and Territories. Information on ADAP programs is available at: <http://hab.hrsa.gov/programs/adap/>

DISPROPORTIONATE SHARE HOSPITALS

For purposes of this report, the term “DSH hospitals” is used to represent the concept of safety-net hospitals where low-income individuals (who are either uninsured, dually eligible for Medicare and Medicaid, or covered by Medicaid or other government-subsidized programs) comprise a high proportion of the hospital’s total patient caseload (often 40 percent or more). Such hospitals always or nearly always carry an official designation as a Medicaid and/or Medicare DSH hospital, although the full set of hospitals receiving DSH payment for Medicaid or Medicare may be more inclusive than a set that could be considered core safety-net hospitals based on consensus. Both the Medicare and Medicaid programs offer enhanced reimbursement to designated DSH hospitals using different formulas.

Additional information on DSH hospitals is available at :

<http://www.naph.org/Content/ContentGroups/Publications1/WhatIsASafetyNetHospital.pdf>

http://www.cms.hhs.gov/MLNProducts/downloads/2007_mdsh.pdf

http://www.ssa.gov/OP_Home/ssact/title19/1923.htm

CRITICAL ACCESS HOSPITALS

Critical Access Hospitals (CAHs) must be located in a rural area (or an area treated as rural); be more than 35 miles (or 15 miles in areas with mountainous terrain or only secondary roads available) from another hospital or be certified before January 1, 2006 by the State as being a necessary provider of health care services. CAHs are required to make available 24-hour emergency care services that a State determines are necessary. They may have a maximum of 25 acute care and swing beds, and must maintain an annual average length of stay of 96 hours or less for their acute care patients. CAHs are reimbursed by Medicare on a cost basis (i.e., for the reasonable costs of providing inpatient, outpatient and swing bed services). Information on CAHs is available at: http://www.cms.hhs.gov/CertificationandCompliance/04_CAHs.asp

RURAL HEALTH CLINICS

Rural Health Clinics (RHCs) were first established in 1977 to address an inadequate supply of physicians who serve Medicare and Medicaid beneficiaries in rural areas. The program provides qualifying clinics located in rural and medically underserved communities with payment on a cost-related basis for outpatient physician and certain non-physician services. RHCs are located in areas that are designated by the Secretary of the Department of Health and Human Services as Health Professional Shortage Areas (HPSA) or Medically Underserved Areas (MUA). A clinic cannot be Medicare approved concurrently as a RHC and an FQHC. Information on RHCs is available at: <http://www.cms.hhs.gov/center/rural.asp>

APPENDIX C

CHARACTERISTICS OF CLINICAL PHARMACY PROGRAMS IN FEDERALLY QUALIFIED HEALTH CENTERS, DISPROPORTIONATE SHARE HOSPITALS, AND AIDS DRUG ASSISTANCE PROGRAM SITES

Table C.1 Characteristics of Clinical Pharmacy Programs in Federally Qualified Health Center Case Study Sites ¹

Year Program Began	Community Health Association of Spokane Washington	Community Health Centers, Inc. Utah	El Rio Community Health Center Arizona	Miles Square Health Center Illinois	Partnership Community Health Center Montana	Siouxland Community Health Center Nebraska	Westside Community Health Services Minnesota
	9	1 (part-time)	2	1	1 (part-time)	1	1
Number of Clinical Pharmacists							
Targeted Disease States	Diabetes HIV-AIDS Pain management	Primarily diabetes	Primarily diabetes	Primarily diabetes	Asthma HIV-AIDS Anti-coagulation	Primarily diabetes	Diabetes Anti-coagulation Asthma HIV-AIDS
Volume of Patient Encounters Per Month	150-200 AIDS patients, other patient volume difficult to estimate	100-320	320	200	80-120	40-50	80
Other Pharmacist Responsibilities	Dispensing	None, only clinical pharmacy duties	None, only clinical pharmacy duties	Participates in disease collaboratives Formulary review	Backup dispensing pharmacist	Director of 4 disease collaboratives Backup dispensing pharmacist	Dispensing
Primary Challenges							
Lack of awareness or resistance among providers	X		X		X	X	X
Recruitment/retention of pharmacists	X		X			X	X
Financing		X	X		X	X	
Patient language barriers		X		X			X
Space constraints		X	X	X	X	X	X
Integrating electronic records	X	X					
Funding Sources							
Dispensing Revenues	X		X			X	X
Medicare Part B "incident to" billing							
Medicare Part D MTM						X	X
Medicaid						X	X
Grants and Donations			X				X
University partner		X			X	X	X
Patient co-payments		X				X	X
General budget funds		X		X		X	X

Relationships with College of Pharmacy	Washington State University: Telepharmacy student training program.	University of Utah: Shared faculty member and on-site student training.	University of Arizona: On-site student training and residencies.	University of Illinois: On-site student training and research support.	University of Montana: Shared faculty member and on-site student training.	University of Nebraska: Shared faculty member and on-site student training.	University of Minnesota: On-site student training and residency program.
<p>Reported Outcomes</p>	<p>Creighton University: On-site student training.</p> <p>Report reduced prescribing errors, and have achieved 85% generic prescribing rate.</p>	<p>Statistically significant improvements, relative to control group, in number of patients with diabetes meeting clinical control guidelines for HbA1c and HDL-cholesterol levels.²</p>	<p>For patients with diabetes, sevenfold increase in percentage meeting goals for blood glucose control.³ Statistically significant reductions, relative to control group, in HbA1c and lipid levels.⁴ Improvements in provider efficiency also noted.</p>	<p>Impact on quality expected to help health center in future P4P initiatives.</p>	<p>Currently conducting evaluation of asthma intervention.</p>	<p>Statistically significant improvements, relative to control group, in patient satisfaction and number of patients with diabetes meeting clinical control guidelines for HbA1c and cholesterol levels.⁵ Improvements in provider efficiency and 340B program management also noted.</p>	<p>Better patient understanding of medications, and more appropriate use of medications.</p>
<p>Future Plans and Other Observations</p>	<p>Plans to start providing anti-coagulation clinic, smoking cessation program, Medicare Part D MTM services.</p>	<p>No on-site pharmacy, long-term stability of program questionable.</p>	<p>Target areas for expansion include asthma, pain management, and pediatrics.</p>	<p>Will continue acting as resource to other safety-net providers in community.</p>	<p>Plans to begin providing Medicare Part D MTM services.</p>	<p>Plans to start an anti-coagulation clinic.</p>	<p>Provide MTM services. Plans to increase pharmacy automation to free up time for patient care and increase encounter volume.</p>

¹ Unless otherwise noted, information was obtained through interviews with health center pharmacists and administrative staff, which were conducted during August-October 2007.

² Laura Shane-McWhorter and Gary Oderda. "Providing Diabetes Education and Care to Underserved Patients in a Collaborative Practice at a Utah Community Health Center." *Pharmacotherapy*. 2005. 25(1): 96-109.

³ Sandra Leal, Jon Glover, Richard Herrier, Anthony Felix. "Improving Quality of Care in Diabetes Through a Comprehensive Pharmacist-Based Disease Management Program." *Diabetes Care*. December 2004. 27(12): 2983-2984.

⁴ Elizabeth Hogan, Sandra Leal, Marion Slack, David Apgar. "Diabetes drug management: pharmacists vs. physicians." *Hospital Pharmacy Europe*. July/August 2006. Pp.16-17.

⁵ David Scott. Steven Boyd, Michelle Stephan, Sam Augustine, Thomas Reardon. "Outcomes of pharmacist-managed diabetes care services in a community health center." *American Journal of Health-Systems Pharmacists*. November 2006. 63: 2116-2122.

Table C.2 Characteristics of Clinical Pharmacy Programs in Disproportionate Share Hospital Case Study Sites ¹

	Boston Medical Center Massachusetts 2004	Grady Health System Georgia 2002	Harris County Hospital/District Texas 1999	Huey Long Hospital Louisiana 1996	Parkland Hospital Texas 1996	Shands Hospital Florida 1980s
Year Program Began	2004	2002	1999	1996	1996	1980s
Number of Clinical Pharmacists	Multiple (no specific number given)	3 (plus 1 resident)	10	1 (plus 2 residents)	14	10
Targeted Disease States	Diabetes COPD, Asthma Hypertension, Lipids	Diabetes Heart failure Deep vein thrombosis	Primary care HIV-AIDS Anti-coagulation	Anti-coagulation Dyslipidemia Diabetes	Primary care clinics Anti-coagulation Lipid, Asthma, HIV, Geriatrics, Allergy	Diabetes Anti-coagulation Pain management
Volume of Patient Encounters Per Month	120-160	400	Primary care: 1,200	Anti-coagulation: 600 Lipid clinic: 160-200	Primary care: 80-130	Anti-coagulation: 450
Other Pharmacist Responsibilities	Dispensing	Dispensing	None, only clinical pharmacy duties	None specified	Most are full time clinical pharmacists	Dispensing Teaching, training of students & residents at hospital
Primary Challenges						
Lack of awareness or resistance among providers	X		X	X	X	
Recruitment/retention of pharmacists		X			X	X
Financing	X	X	X	X		X
Patient language barriers						
Space constraints		X			X	X
Integrating electronic records	X	X				
Funding Sources						
Dispensing Revenues	X	X		X	X	X
Medicare Part B "incident to" billing					X	
Medicare Part B facility fees			X			X
Medicare Part D MTM	X	X		X	X	X
Medicaid		X		X	X	
Grants and Donations				X		
University partner			X	X		X
Patient co-payments		X	X		X	X
General budget funds					X	X

Table C.2 Characteristics of Clinical Pharmacy Programs in Disproportionate Share Hospital Case Study Sites ¹

Relationships with College of Pharmacy	None specified.	<p>Mercer University, Southern College of Pharmacy: On-site student training.</p> <p>Texas Southern University: On-site student training, shared faculty and pharmacy operations manager</p> <p>University of Houston: On-site student training.</p>	<p>University of Louisiana-Monroe: Residency program. Faculty members provide consulting services to the hospital, work with residents on projects within clinics.</p>	<p>University of Texas-Austin, University of Houston: On-site student training.</p>	<p>University of Florida: On-site student training. Residency program.</p>
Reported Outcomes	<p>No system to track outcomes. Some evidence that services are reducing hospitalizations and reducing HbA1c among patients with diabetes.</p>	<p>600 hospitalizations avoided (\$660,000 in cost avoidance) through DVT program. Potential cost avoidance of \$200,000 over 5 months via heart failure clinic.</p>	<p>Reduced average HbA1c levels, and \$1.5 million in cost savings from ER and hospital visit reductions in diabetes population. Improvements in physician efficiency also noted.</p>	<p>Outcomes studies underway.</p>	<p>Cost-benefit study underway.</p> <p>No documented outcomes. Staff believe services save money for the facility by reducing ER visits, admissions.</p>
Future Plans and Other Observations	<p>Clinical pharmacists viewed as mid-level providers.</p>	<p>Physicians find the services quite valuable. Better information technology is desired to more effectively track outcomes.</p>	<p>Some clinical pharmacy services are delivered through nearby network of community health centers, with direct referral from hospital discharges. Plan to provide Medicare MTM services in the future.</p>	<p>Medical staff is quite supportive of services.</p>	<p>Reimbursement from Part D PDPs have been delayed. Perception that MTM is set up for retail pharmacies.</p> <p>Commented that change in patient definition under 340B program may reduce available revenue.</p>

¹ Unless otherwise noted, information was obtained through interviews with hospital pharmacists and administrative staff, which were conducted during August-October 2007.

Table C.3 Characteristics of Clinical Pharmacy Programs in AIDS Drug Assistance Program (ADAP) Case Study Sites ¹

	2002	2007	1998	2004	2001
Year Program Began	1	1	1	2	3
Number of Clinical Pharmacists	1	1	1	2	3
Targeted Disease States	HIV-AIDS	HIV-AIDS	HIV-AIDS, Hepatitis C HIV-AIDS with comorbid conditions	HIV-AIDS, comorbid conditions	HIV-AIDS
Volume of Patient Encounters Per Month	80-90	120 (number of patients enrolled in clinic)	50-60	80-120	All 2000 clients in the direct-purchase program are monitored.
Other Pharmacist Responsibilities	None specified.	None specified.	No dispensing duties.	Dispensing	Dispensing
Primary Challenges					
Lack of awareness or resistance among providers	X			X	
Recruitment/retention of pharmacists	X				
Financing	X			X	
Learning curve of HIV specialty		X			
Insufficient staffing			X		
Patient language barriers		X			X
Space constraints				X	
Integrating electronic records				X	
Funding Sources					
Dispensing Revenues			X		
Medicare Part B "incident to" billing			X		
Medicare Part D MTM					
Medicaid			X		
Grants (ADAP) and Donations	X	X	X	X	X
University partner	X				
Patient co-payments					
General budget funds					X

Bond Community Health Center, Inc. Florida
Westside Community Health Services Minnesota
Infectious Disease Program Grady Health System Georgia
Whitman-Walker Clinic Washington, D.C.
Central/Elli Pharmacy 2 South Carolina

Table C.3 Characteristics of Clinical Pharmacy Programs in AIDS Drug Assistance Program (ADAP) Case Study Sites¹

Relationships with College of Pharmacy	Florida A&M University: Residency program.	No current relationships.	None specified.	University of Maryland; Howard University; Philadelphia College of Pharmacy: On-site student training.	No current relationships.
Reported Outcomes	None documented.	Patients receiving pharmacist-delivered adherence counseling had statistically significant decrease in HIV-RNA and increase in CD4 cell counts. Viral suppression was 82% relative to 57% for the control group (borderline statistical significance, $p=0.12$). ³	Improvements in physicians efficiency noted.	None documented. Pharmacist stated that viral loads are under control for her patients.	None documented.
Future Plans and Other Observations	Believe that patient resistance to medication is more likely to be discovered with pharmacist, as MDs less likely to test.	High patient satisfaction.		Pharmacists work closely with case managers to serve patients.	

¹ Unless otherwise noted, information was obtained through interviews with ADAP pharmacists and administrative staff, which were conducted during August-October 2007.

² In South Carolina, adherence monitoring and telephone follow-up for non-adherent HIV-AIDS patients are conducted by the state-run central fill pharmacy. Services are only available to patients served under the direct purchase program, not those served by the rebate program.

³ Deanna Gengler, Dan Rehrauer, and Todd Sorensen. "Modified Directly Observed Therapy in HIV Patients: an observational study in a community health center." Unpublished paper completed in fulfillment of residency requirements. University of Minnesota, August 2, 2005.

APPENDIX D

**REPORTS FROM THE FIELD: SELECTED
CASE STUDY SITES REPORTING SUCCESS**

1. HARRIS COUNTY HOSPITAL DISTRICT, HOUSTON, TX

Background: The Harris County Hospital District (HCHD) is the public health care system for the nation's third most populous county. Annually, the district provides more than 1 million health care visits to uninsured, underinsured, and medically needy residents of Harris County, including a large Spanish-speaking population. It operates three major hospitals, 12 community health centers, 13 homeless shelter clinics, eight school-based clinics, a dental center, and four mobile health units.

Clinical Pharmacy Services (begun in 1999): HCHD employ eight full-time-equivalent primary care clinical pharmacists, who are located in community health centers and work based on physician referrals for patients with any chronic disease. HCHD also employs one HIV specialist and one anticoagulation specialist. Clinical pharmacists work under a collaborative practice agreement so they can adjust or cancel medications (but not initiate new ones). They educate, monitor, review and adjust medications following protocols that have been developed for every major disease state based on national clinical guidelines, with a particularly detailed one for diabetes. Overall, about a third of the patient population receives clinical pharmacy services.

Clinical Outcomes Reported: Not quantified, but "for the patients, their disease is in control, and they understand more about their disease..."

Other Outcomes Reported: HCHD reports documenting \$1.5 million in cost savings in 2005 alone from emergency department and hospital visit reductions in the diabetes population who received clinical pharmacy services, compared to patients who were scheduled for these services but did not keep their appointments. Patients are also reported to benefit: "The patients are getting cost-savings because our pharmacists are always looking for more cost-effective medications for them." Regarding physicians, having the clinical pharmacists allows them to see more complex patients, helps meet high demand for services, and helps keep down wait times because there are fewer follow-up appointments.

2. WESTSIDE COMMUNITY HEALTH SERVICES, ST. PAUL, MN

Background: Westside Community Health Services (WCHS) includes three primary care clinics, as well as school-based clinics, services within homeless shelters, and two dental clinics. WCHS serves over 35,000 patients annually, including large Latino and Hmong populations, St. Paul public housing residents, people in the homeless population, and adolescents in the St. Paul metropolitan area.

Clinical Pharmacy Services (begun in 2001): Services provided by three clinical pharmacists and a full-time pharmacy resident include medication therapy management, an HIV medication adherence program, and asthma and diabetes education. They also participate in geriatric and diabetes clinics, and serve as an information source for providers. Working under a protocol, the clinical pharmacist can alter a medication to a different medication in the same therapeutic class. In addition, collaborative practice agreements allow the pharmacist to adjust medications according to protocols for anticoagulation, dyslipidemia, and HIV. The health center provided approximately 1,000 clinical pharmacy visits last year to patients referred by their medical provider, identified by a pharmacist, or identified after chart review by the clinical pharmacist.

Clinical Outcomes Reported: Under the pharmacist-run HIV medication adherence program, 82 percent of patients studied for a 13-month period showed viral suppression (HIV RNA \leq 75 copies/ml using the Versant HIV-1 RNA v3.0 test), compared with only 57 percent of the patients who did not receive the services (Gengler 2005). Thirty-one patients participated in the study. Qualitatively, staff also report observing better patient understanding of medications and more appropriate use of medications. In a separate effort, a clinical pharmacy resident documented and resolved 55 drug therapy problems in just 16 patients with rheumatoid arthritis (Skoglund 2005).

Other Outcomes Reported: More cost-effective medication use, and ensuring Medicare patients are enrolled in an appropriate Medicare Part D plan.

3. EL RIO COMMUNITY HEALTH CENTER, TUCSON, AZ

Background: El Rio serves over 70,000 patients in Tucson and the surrounding area through five general primary care clinics, as well as three school-based clinics, an urgent care center, and seven other clinics including women's health, pediatrics, immunology, behavioral health, and dental services. The population served includes a high proportion of Mexican-Americans and many Native Americans from the Pasqua Yaqui tribe.

Clinical Pharmacy Services (begun in 2001): Two clinical pharmacists at two sites see about 80 patients per week who are referred by their physician. The primary focus is diabetes and co-morbid conditions. The pharmacists conduct extensive education, review of patients' entire set of medications, and monitoring (such as HbA1c testing), and make medication changes as needed consistent with a protocol. In keeping with Arizona law, the pharmacists are able to prescribe consistent with a collaborative protocol, which was developed together with El Rio's physicians and based on American Diabetes Association clinical guidelines.

Clinical Outcomes Reported: The percentage of patients with diabetes with good HbA1c control increased dramatically after receiving the services—almost seven-fold, from 6 percent to 41 percent (Leal et al. 2004). Significant improvements in HbA1c and lipid levels were also found relative to a comparison group receiving usual care at a hospital outpatient department (Hogan et al. 2006).

Other Outcomes Reported: Having the clinical pharmacists helps free up the physicians so they can better meet very high patient demand for services.

APPENDIX E

**STATE MEDICAID PROGRAM PAYMENT FOR
CLINICAL PHARMACY SERVICES**

Table E.1 Clinical Pharmacy Services Reimbursed by State Medicaid Programs ¹

Year Program Implemented	Minnesota 2005	Missouri (1) 2003; (2) 2008	Iowa 2000	Florida 2008	North Carolina (1) 2002; (2) 2006	Wisconsin 1995	Mississippi 1998	Utah 2008
Program Name	Medication Therapy Management	(1) Pharmacy-Assisted Collaborative Disease Management (2) Chronic-Care Improvement Program	Pharmaceutical Case Management	Medication Therapy Management	(1) Nursing Home Polyparmacy (2) Focused Risk Management Program	Pharmaceutical Care Program (some clinical services provided through this enhanced dispensing fee program)	Pharmacy Disease Management	PharmacoTherapy Risk Management System
Program Authorization	State Plan Amendment, with enabling legislation in 2005. Result of advocacy by Minnesota Pharmacy Association and group at University of Minnesota.	State Plan Amendment in 2002, implemented as part of larger effort to manage pharmacy benefits.	State Plan Amendment, with enabling legislation in 2000. Result of advocacy by Iowa Pharmacy Association and State Representative.		(1) Pilot program through ACCESS, North Carolina's Medicaid Managed Care Program (NC 2.4). (2) State Plan Amendment in 2007 (NC 6).	State Plan Amendment, requirement in 1995 state biennial budget.	Medicaid Waiver in 1998, State Plan Amendment in 2002 (MS 3, 4).	Funded as part of 2007 Medicaid Transformation Grant, which supported development of electronic surveillance tool (UT 2).
Reimbursement System	Initial consultation and 7 follow-up visits per year. Uses Medicare Part D MTM codes as basis; payments range from \$34-\$148 per visit and depend on complexity of patients and number of issues identified (MN 3).	(1) Initial visit at \$50, and up to two follow-up visits at \$15 each. (2) Payment for each intervention.	Initial assessment, up to 4 follow-ups per year, up to 2 new problem assessments per year, and up to 1 preventative follow-up every six months. Maximum of 9 billings, total of \$365 per patient per year (IA 3).	Plan for 3 reimbursement rates: initial patient encounter (highest), follow up, and additional time spent with patient. Specific dollar amounts have not been established. Reimbursements will go to the pharmacy, which will determine how and if payments will be disseminated to individual pharmacists.	(1) One-time payment of \$12.50 for consultant pharmacists to review and document charts, \$6.25 for prospective review (NC 7). (2) \$30 per patient per quarter fee to provide MTM services (NC 5).	Enhanced dispensing fees range from \$9.45 to \$40.11, depending on reason for consultation and length of consultation. Each can only be billed between 1 and 4 times per patient per year (WI 2).	Reimbursed \$20 for each encounter. Encounters must be at least 15 minutes long and average 30 minutes. Maximum of 12 encounters per beneficiary per year (MS 3, 5).	Appointments of 30-60 minutes. Medicaid billed \$30-\$90 per visit, depending on length and intensity of interactions.

<p>Involvement of Medicaid Managed Care</p>	<p>Only available to fee-for-service Medicaid beneficiaries in 2006. In 2007, incorporated into the managed care contract.</p>	<p>No indication that this interfaces with Medicaid Managed Care.</p>	<p>Only available to FFS Medicaid beneficiaries.</p>	<p>(1) Implemented through North Carolina's Medicaid Managed Care program (NC 2.4). (2) No indication that this interfaces with Medicaid Managed Care.</p>	<p>No indication that this interfaces with Medicaid Managed Care.</p>	<p>Only available to FFS Medicaid beneficiaries.</p>
<p>Involvement of FQHCs</p>	<p>FQHCs not reimbursed on a per-encounter basis. Cost of providing service incorporated into overall per-encounter rate that FQHCs receive.</p>	<p>FQHCs not reimbursed on a per-encounter basis. Cost of providing service incorporated into overall per-encounter rate that FQHCs receive.</p>	<p>FQHCs eligible to participate in this program.</p>	<p>(1) No involvement (2) Not clear whether FQHCs are eligible</p>	<p>Does not interface with FQHC payments.</p>	<p>FQHCs eligible to participate in this program.</p>
<p>Eligible Patient Population and Extent Reached</p>	<p>Beneficiaries with at least 4 medications used to treat at least 2 chronic conditions (MIN 3). In 2006, 259 out of estimated 5600 eligible beneficiaries were reached.</p>	<p>Beneficiaries who take four or more medications and have one of twelve selected disease states. In 2002, 943 of 3,037 eligible patients reached by pharmacist (IA 2).</p>	<p>Criteria for eligibility have not been fully defined. Likely to target patients with specific disease states who have an identified medication quality-related event, rather than basing the intervention on the number of prescriptions a beneficiary takes.</p>	<p>(1) Nursing home patients with more than 18 prescription fills in 90 days (NC 7). (2) Patients with 11 or more medications, must receive all medications at the same pharmacy (NC 5).</p>	<p>Beneficiaries with diabetes, asthma, hyperlipidemia, or those receiving anti-coagulation therapy. Patients are referred by their physicians. Evaluation in 2003 had 75 asthma patients, 80 diabetes patients.</p>	<p>Beneficiaries with four or more chronic diseases, multiple problems, or who are at high risk for developing adverse drug events. Plan to reach about 600 patients (UJ 2).</p>

<p>Pharmacist Credentialing/ Training Required</p>	<p>Graduation with Pharmacy Diploma after May 1996, or completion of program approved by Accreditation Council of Pharmacy Education (MN 3).</p>	<p>Certification as a pharmacist with Missouri, which involves 8 hours course work, and online training on point-of-service system that will be used to implement program.</p>	<p>Professional training regarding patient-oriented medication-related problem prevention and resolution (Doctorate of Pharmacy sufficient, or can complete course from Iowa Center for Pharmaceutical Care) (IA 3).</p>	<p>No pharmacist credentialing is required. Medicaid will provide conferences starting in February 2008 to describe the program to interested pharmacists, who are responsible for training individual pharmacists.</p>	<p>No indication of additional training required.</p>	<p>No additional training required.</p>	<p>Completion of a disease-specific certification program approved by the Mississippi Board of Pharmacy (MS 5).</p>	<p>Completion of a certificate program designed by the Drug Regimen Review Center at the University of Utah, College of Pharmacy (UT 2).</p>
<p>Plans for Change in the Future</p>	<p>Considering targeting (not limiting) program to certain disease states. Considering more explicit involvement of physicians.</p>	<p>Planning to integrate pharmacy component into already existing physician-targeted pay-for-performance program.</p>	<p>Reviewing how to integrate this program with disease management and primary care case management programs.</p>	<p>Not applicable.</p>	<p>No response.</p>	<p>Wisconsin Medicaid is part of the Wisconsin Pharmacy Collaborative, which is exploring a possible MTM pilot project.</p>	<p>No response.</p>	<p>Not applicable.</p>
<p>Reported Outcomes</p>	<p>Evaluation of first program year forthcoming. Average of more than 3 drug therapy programs identified per patient and significant improvement in percentage of participants with diabetes who met Wisconsin diabetes care clinical goals (WI 2).</p>	<p>Return-on-investment of 2.5:1. In State FY06, saw slower growth in ER and hospitalization rates among treatment group, estimated savings of \$429 per member per month (MO 2).</p>	<p>Statistically significant improvements in patient safety. No net increase in healthcare utilization or charges among patients receiving PCM. Possible emergency room and outpatient facility utilization decrease for patients of pharmacies who adopted PCM most intensely (IA 2).</p>	<p>Plan to have outcomes measures, but not sure about specifics.</p>	<p>(1) \$16 million in annual savings and 13:1 return on investment (NC 1), average of more than one recommendation for therapeutic changes per participant (NC 3, 7)</p>	<p>For enhanced dispensing fee program, as a whole, have realized cost savings for pharmacy claims. Program includes "built in" cost savings, like therapeutic substitution; have not analyzed clinical interventions separately.</p>	<p>Decreased hospital admissions and ER visits (MS 2).</p>	<p>Evaluation of quality and cost impacts will take place as part of pilot program. Results scheduled for 2009.</p>

¹ Unless otherwise noted, data were obtained through interviews with Medicaid agency representatives from each state.

State	References
Minnesota	<p>(1) Minnesota Medicaid Staff. Personal interview. November 15, 2007.</p> <p>(2) Brian Isett. University of Minnesota. Personal interview. December 7, 2007.</p> <p>(3) "Minnesota Health Care Programs Provider Manual. Chapter 22a: Medication Therapy Management Services." Accessed December 7, 2007. Available at http://www.dhs.state.mn.us/main/dhs16_136889.</p>
Missouri	<p>(1) Missouri Medicaid Staff. Personal interview. November 1, 2007.</p> <p>(2) George Oestreich. "MO HealthNet MTM." Presentation delivered at American Pharmacists Association and National Chain Drug Store Association meeting, "Community Pharmacy: Building Process, Partnerships, and Outcomes." September 19, 2007.</p>
Iowa	<p>(1) Iowa Medicaid Staff. Personal interview. November 29, 2007.</p> <p>(2) Elizabeth Chrischilles, Barry Carter, Margaret Voelker, David Scholz, Shari Chen-Hardee, Linda Rubenstein, Tae-Ryong Park, Brian Lund, Angela Kuehl, Gary Rosenthal, and Joseph Hanlon. "Iowa Medicaid Pharmaceutical Case Management Program: Report of the Program Evaluation." December 2002. Accessed October 25, 2007. Available at http://www.iarx.org/Documents/PCM%20Final%20Report.pdf.</p> <p>(3) "Iowa Medicaid Pharmaceutical Case Management." Iowa Pharmacy Association. Accessed October 25, 2007. Available at http://www.iarx.org/iowaPharmacy/Foundation/PCM.aspx.</p>
Florida	<p>(1) Florida Medicaid Staff. Personal interview. November 21, 2007.</p>
North Carolina	<p>(1) California Healthcare Foundation. "Disease Management in Medicaid." 2004. Accessed December 10, 2007. Available at http://www.chcf.org/documents/policy/DiseaseManagementInMedicaid2004.pdf.</p> <p>(2) Carmen Hooker Odom and Torlen Wade. "The Department of Health and Human Services: Medicaid Pharmacy Management Strategy 2003-2005. <i>North Carolina Medical Journal</i>. December 2003. 64(6): 278-279.</p> <p>(3) Dale Christensen, Troy Trygstad, Robert Sullivan, Jennifer Garmise, and Steven Wegner. "A pharmacy management intervention for optimizing drug therapy for nursing home patients." <i>The American Journal of Geriatric Pharmacotherapy</i>. December 2004. 2(4):248-256</p> <p>(4) Division of Medical Assistance. "History of North Carolina Medicaid Program: State Fiscal Years 1970-2006." Accessed December 10, 2007. Available at http://www.dhhs.state.nc.us/dma/historyofmedicaid.pdf.</p> <p>(5) Division of Medical Assistance. "North Carolina Special Bulletin." July 2007. Accessed December 10, 2007. Available at http://www.ncdhhs.gov/dma/bulletin/PharmacyBulletin0707.pdf.</p> <p>(6) North Carolina Division of Medical Assistance. "State Plan." Accessed December 10, 2007. Available http://www.dhhs.state.nc.us/dma/sp.htm.</p> <p>(7) Troy Trygstad, Dale Christensen, Jennifer Garmise, Robert Sullivan, and Steven Wegner. "Pharmacist response to alerts generated from Medicaid pharmacy claims in a long-term care setting: results from the North Carolina Polypharmacy initiative." <i>Journal of Managed Care Pharmacy</i>. September 2005. 11(7): 575-83.</p>
Wisconsin	<p>(1) Wisconsin Medicaid Staff. Personal interview. December 6, 2007.</p> <p>(2) "Wisconsin Medicaid Pharmacy Handbook: Drug Utilization Review and Pharmacy Care Section." July 2001. Accessed December 10, 2007. Available at http://dhfs.wisconsin.gov/Medicaid2/handbooks/pharmacy/dur/durframe.htm.</p>
Mississippi	<p>(1) Mississippi Medicaid Staff. Personal interview. October 25, 2007.</p> <p>(2) Donna Young. "Promising results revealed in Mississippi disease management program." <i>American Journal of Health Systems Pharmacists</i>. September 2003. 60: 1720-1724.</p> <p>(3) Marlene Z. Bloom. "Mississippi Medicaid waiver breaks new ground for pharmacists." <i>Journal of Managed Care Pharmacy</i>. 1998. 4(6). Accessed December 10, 2007. Available at http://www.amcp.org/data/jmcp/vol4/num6/.</p> <p>(4) Mississippi Division of Medicaid. "State Plan, Attachment 3-1.A: Amounts, Duration, and Scope of Medical Care Provided." Accessed December 10, 2007. Available at http://www.dom.state.ms.us/State_Plan/Table_of_Contents/table_of_contents.html. pp.28-29.</p> <p>(5) Mississippi Division of Medicaid. "Provider Policy Manual. Section 31.39: Pharmacy Disease Management." Accessed December 10, 2007. Available at http://www.dom.state.ms.us/ProviderManuals/Section.aspx?Provider/Provider_Manuals/Manuals/Section%2031%20-%20Pharmacy.</p>
Utah	<p>(1) Utah Medicaid Staff. Personal interview. November 28, 2007.</p> <p>(2) Division of Health Care Financing. Utah Department of Health. "Proposal for a Medicaid Transformation grant: Developing a Utah pharmacotherapy risk management system with an electronic surveillance tool (Utah ePRM)." Submitted to the Centers for Medicare & Medicaid Services. October 2, 2006.</p>

