



Credentialing and privileging for clinical pharmacists

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Abstract

The American College of Clinical Pharmacy (ACCP) 2019 Certification Affairs Committee was charged with writing a white paper to provide a road map for developing initial and ongoing credentialing and privileging processes for clinical pharmacists. After extensively reviewing the literature, the committee prepared a framework to support organizations in implementing credentialing and privileging programs. This document contains definitions, principles, and a suggested process for credentialing; organizational costs of credentialing and privileging; and barriers associated with the process. Finally, resources are provided to help the reader establish a credentialing and privileging process.

KEYWORDS

clinical pharmacist, credentialing, privileging

1 | INTRODUCTION

The American College of Clinical Pharmacy (ACCP) has long advocated a highly trained clinical pharmacy workforce. ACCP believes that clinical pharmacists “should possess the education, training, and experience necessary to function effectively, efficiently, and responsibly in the [direct patient care] role.”¹ The question becomes, how does the clinical pharmacist accomplish that goal? The College's 2017 Strategic Plan asks how ACCP will position clinical pharmacists to fully contribute their expertise to direct patient care by optimally collaborating with the interprofessional team and patients.² As such, ACCP advocates for the credentialing and privileging of clinical pharmacists providing

comprehensive medication management and direct patient care. This white paper provides a road map for organizations to develop and implement initial and ongoing credentialing and privileging processes for clinical pharmacists.

2 | DEFINITIONS

It is important to understand the terminology associated with *credentialing* and *privileging* because these terms can easily be incorrectly interchanged with *competence* and *competencies*. Merriam-Webster defines “competence” as the quality or state of being competent such as having sufficient knowledge, judgment, skill, or strength in a particular respect.³ ACCP defined five core clinical competencies in 2008,⁴ updating them to include six core competencies in 2017.¹ The six core areas consist of elements of competency for direct patient care, pharmacotherapy knowledge, systems-based care and population health, communication, professionalism, and continuing professional development.¹

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The Council on Credentialing in Pharmacy defines credential, credentialing, and privileging as follows⁵:

- **Credential:** Documented evidence of professional qualifications.
- **Credentialing:** The process of granting a credential; or the process by which an organization or institution obtains, verifies, and assesses an individual's qualifications to provide patient care services.
- **Privileging:** The process by which a health care organization, having reviewed an individual health care provider's credentials and performance and found them satisfactory, authorizes that person to perform a specific scope of patient care services within that organization.

Therefore, a credential such as a degree, a license to practice pharmacy, a postgraduate training certificate, or a program certificate may be granted after verification of competence in a specified area. This paper will focus on credentialing as the verification of accuracy and currency for credentials that are claimed by a professional.

3 | BACKGROUND

The process of credentialing and privileging is well established as a critical component of physician quality assurance. Implementing comprehensive credentialing programs for all health care professionals, including clinical pharmacists, is an important safety measure to optimize patient outcomes by ensuring the integrity of an appropriately trained and experienced clinical workforce.

Credentialing and privileging processes for physicians are generally managed by a medical staff office (MSO), often working under the authority of the Medical Executive Committee of the medical staff. In 2012, the Centers for Medicare & Medicaid Services (CMS) expanded the definition of "medical staff" to allow organizations to include other professions in their standard processes, provided they are consistent with state law.^{6,7} Therefore, understanding the state laws related to credentialing and privileging and considering the applicable scope of practice for health professionals are imperative. These laws may include statements about required credentials or frequency of appraisal and reappraisal of competence.

The concept of privileging is not new to clinical pharmacy. ACCP has advocated a process to privilege clinical pharmacists providing comprehensive medication management and direct patient care and endorsed the recommendations for credentialing critical care.⁸ The Department of Veterans Affairs (VA) has established a rigorous credentialing and privileging process for clinical pharmacists.⁹ Many other health care organizations and institutions have developed internal competency assessment programs. Common examples are pharmacokinetic or warfarin management training and assessment programs. These programs generally incorporate an educational session and demonstration of competence and, on completion, offer the opportunity to perform a service independently. Such pathways fall just short of formal privileging systems.

4 | PRINCIPLES FOR POST-LICENSURE CREDENTIALING: THE CREDENTIALING PROCESS

4.1 | Basic credentialing process

4.1.1 | The medical model

The medical model for credentialing is a quality assurance process for medical staff that is understood and recognized by physicians, insurers, and health systems. Verifying a provider's qualifications through a credentialing process may also help protect organizations against malpractice allegations.¹⁰ Although institutions drive the specific policies and procedures for credentialing, the credentialing process is guided and mandated by accrediting bodies like The Joint Commission (TJC) and payers such as CMS. Each state has different requirements for licensure and laws defining who can practice as a licensed independent practitioner (LIP), to whom the credentialing process will apply. For example, in some states, nurse practitioners are LIPs, whereas in other states, they must practice under the supervision of an otherwise defined LIP. Furthermore, the credentialing process varies by type of practitioner and area of practice.

4.1.2 | Clinical pharmacist credentialing

In May 2012, CMS modified its definition of "medical staff" to include non-physician practitioners.⁶ This expansion allowed the inclusion of clinical pharmacists as credentialed and privileged practitioners within a health system in accordance with state laws and institutional bylaws governing medical staff.¹¹ This ruling provides clinical pharmacists with the opportunity to provide patient care and perform clinical activities as designated within the pharmacy practice act for any given state. Traditionally, pharmacist credentialing has been limited to verification that the pharmacist graduated from an accredited school of pharmacy and has a current pharmacy license in good standing.¹² However, expanded clinical responsibilities and an increasingly complex health care system call for an expanded credentialing process to ensure that clinical pharmacists practicing in such roles have the knowledge and skills necessary to provide care in a team-based environment. In addition, use of a credentialing process for clinical pharmacists that mirrors the process used by physicians and other providers promotes consistency and increases understanding and credibility among providers, insurers, and health systems.^{13,14}

Pharmacists should lead an institution's development of clinical pharmacist credentialing and the process should involve key stakeholders. Alternatively, the organization may add clinical pharmacists to an existing formalized credentialing process and consider a change in organizational structure to position clinical pharmacists within a division of the medical staff.¹¹ For example, some mental health settings have a multi-professional credentialing committee composed of psychiatrists, other physicians, psychologists, therapists with various credentials, master of social work professionals, nurse practitioners,

and clinical pharmacists. Integrating clinical pharmacists into an existing process will offer the opportunity for credentialing clinical pharmacists with specific authorities within the scope of practice allowed by state law, thereby authorizing privileges and facilitating interprofessional collaboration. An integrated credentialing process that confers specific clinical privileges and authorities within the health system can pave the way for reimbursement from payers.¹⁵ However, integrating clinical pharmacists into the medical staff may also have disadvantages. Physicians have levels of autonomy and influence that may not be shared with clinical pharmacist staff members. In addition, interprofessional competition may create challenges in certain settings.¹⁶

Whether developing a new process for credentialing or adopting a process already in place, several crucial steps should be integrated into the process^{16,17}:

- Define the scope of care provided within the health-system organization. This should consider the setting, the population that will be served, and the services that will be offered.
- Identify the pharmacist's scope of practice as defined by state law.
- Determine the scope of practice for clinical pharmacists (including pharmacists with different credentials) within the organization. This should include the duties or tasks that a specific pharmacist can perform and the amount of oversight provided by prescribers, as allowed by state law, because this will drive the credentials needed to fulfill that role.
- Define the qualifications and competencies necessary to provide quality care for the tasks, duties, or privileges designated in the scope of practice. These qualifications will become the criteria that make up the credentialing process.

The process should outline each of these four elements. Documentation forms to gather the information and checklists to verify that all elements of required documentation are included should be developed and included as part of the process. A method for evaluating and verifying credentials should be specified. Once the aforementioned items have been developed, the credentialing process should be approved and endorsed by the appropriate committees or leadership within the institution.¹⁸

4.1.3 | Criteria for credentialing

The credentialing process can be initiated using an application before hire.¹¹ If an employee moves into a new role with expanded responsibilities with the same employer, an application similar to that used for a new hire to start the credentialing process should be employed. Required credentials will vary with the organization and the pharmacist's scope of practice. The application should contain the following information:

- Basic demographics and contact information.
- Identifying information (eg, social security number and/or a photo ID) to verify the accuracy of applicant identity.

- Work history.
- Education and training.
- Licenses and certifications.
- Information pertaining to any disciplinary actions brought against the applicant's license.
- Personal health status and whether this might affect the applicant's ability to perform specified duties (note: in some cases, applicants may be asked to undergo a health evaluation as part of the credentialing process, whereas in most cases, attestation of health status is acceptable).
- Professional liability insurance information and coverage specifics.
- Written explanation of any involvement in proceedings where malpractice is, or was, alleged.
- Contact information for professional references, specifically peers who directly observed the applicant.
- Other information deemed necessary by state law or an institution.

Sample templates for credentialing and privileging have been developed by Blair et al.¹⁷ These authors note that the templates are comprehensive and include many items that may not be necessary at a given institution or practice site.

4.1.4 | Verification processes

Once the application for credentialing is complete and all supporting documents are received, the materials must be reviewed by human resources, a designated department, or a credentialing committee. Applicant attestation may be recognized as acceptable verification for some elements of the application (eg, applicant's health status), whereas many credentials will need to be verified. The verification process helps ensure that the applicant is who he or she claims to be, the individual has attained the credentials claimed, the credentials are current, and none of the credentials are being disputed.¹⁸

Primary source verification is documentation from the original source of a specific credential that verifies the qualifications are legitimate.¹¹ Primary source verification should be documented for licenses, certifications, education, training, and professional liability insurance.¹¹ Documentation of primary source verification can include a letter, a documented telephone encounter, or a secure electronic communication with the primary source.¹¹ A primary source may designate an agency to verify credentials, at which point the designated agency becomes an acceptable primary source. Primary source verification can also be delegated to an approved external verification source, such as a credentials verification organization (CVO).¹⁹ Accrediting organizations will specify which CVOs are accepted for primary source verification. CVOs such as the American Medical Association Credentialing Services, the American Board of Medical Specialties, and the Federation of State Medical Boards are commonly used for physician credentialing. Pharmacy Profiles, a subsidiary of the American Pharmacists Association, is an example of a CVO specific to pharmacist credentialing.¹⁸ When information cannot be obtained from the primary source, reputable secondary sources may be used.¹⁹

4.1.5 | Evaluation processes

Once all application materials are submitted and deemed complete, a process for review and evaluation is initiated.¹¹ Most organizations will appoint a credentialing department or committee to review the files. Some committees may be made up entirely of members of the medical staff, some may be entirely pharmacists, and others may be interprofessional. In any case, it is important to ensure that pharmacy leadership is actively involved in the process. To ensure the process is thorough, fair, and consistent, policies and procedures should outline the criteria that will be used to make recommendations. It may be helpful to maintain credentialing committee meeting minutes for reference in the event of a challenged decision. Policies and procedures for credentialing should outline a process for notifying applicants of the committee decision, including the notification method (print or electronic writing) and timeframe.

Policies and procedures may include a description of mechanisms and timelines for appealing committee decisions. Applicants generally have the right to inquire about the status of their application, review the information gathered during the application process, and correct any inaccuracies.¹¹ If there are major discrepancies between the information provided by an applicant and the information collected during the verification process, the applicant should be provided an opportunity to explain the discrepancy. Information considered protected because of peer review, as well as information obtained from the National Practitioner Data Bank, cannot lawfully be released to the applicant.¹¹

4.1.6 | Reappraisal processes

In general, credentials must be verified every 2 years to comply with TJC standards.²⁰ CMS mandates recredentialing every 3 years.¹⁹ The timeline selected by an institution for reappraisal should be driven by the payers and accrediting bodies governing that institution, likely every 2 to 3 years. Recredentialing may occur sooner in the case of a change in pharmacist duties or after long absences from practice.^{14,18} It may be desirable to define a timeline and process for recredentialing clinical pharmacists that aligns with the timelines and processes for other medical staff in the institution.¹⁴ To avoid gaps in care, protocols for recredentialing should be established, and specific personnel should be designated to oversee the process. A well-organized process is essential, particularly with larger institutions. This may include using checklists and reminder systems, developing a standardized nomenclature for files, and ensuring adequate storage of files.¹⁹ All documentation should be due well in advance of credential expiration to allow adequate time for review and decision. The process should integrate methods for keeping files updated on qualifications that require renewal, such as licensure or board certification, to ensure all information is current.

See Figure 1 for a summary of the aforementioned steps of establishing a credentialing process.

5 | DEVELOPING CREDENTIALING AND PRIVILEGING PATHWAYS

When no credentialing and privileging pathway has been established, one must be created to standardize practice, establish roles and responsibilities, and provide transparency regarding the clinical pharmacist's role. Various stakeholders should be involved in creating the process.

The appropriate administrator (eg, Chief Pharmacy Officer, Director of Pharmacy, Department Chair) should establish a workgroup that consists of clinical pharmacists from various practice areas with differing responsibilities to help design the credentialing and privileging pathway. This process will allow the workgroup to delineate responsibilities between those with different qualifications and have representation in the process. The director of pharmacy can then engage the upper-level leaders of the hospital or health system to develop a pharmacy credentialing and privileging process that is similar to or integrated with that of other medical staff. Collaboration with the credentialing office, legal affairs, and regulatory affairs is required to verify that the clinical pharmacist's scope of practice conforms to state law and regulations.

In freestanding clinics without a credentialing and privileging process, key stakeholders, including clinical pharmacists, must be involved in creating the protocol. When clinical services are being provided by pharmacist faculty members, academic administration must work with the affiliated health care institutions to ensure that clinical faculty are providing services under an approved credentialing and privileging process.

6 | PRINCIPLES OF PRIVILEGING

The primary rationale for privileging is to optimize patient safety. Ensuring that institutions have defined processes and regulations for a practitioner to become privileged and that its practitioners comply with these regulatory requirements is crucial to both patient safety and institutional accreditation. Of note, although state statutes and regulations address the requirements for entry-level practice, privileging within a health care organization should define elevated or advanced clinical services provided by practitioners such as clinical pharmacists or specialty practice pharmacists (eg, critical care, oncology). Although such services may be unique to a given institution or practice site, they still must follow state practice acts. All pharmacists providing direct patient care should be held to the requirements set forth in the ACCP Standards of Practice for Clinical Pharmacists.^{21,22} Completion of accredited residency training or equivalent post-licensure experience is an expectation, together with board certification once the clinical pharmacist meets the eligibility requirements for the relevant Board of Pharmacy Specialties certification.

Most resources on credentialing and privileging reflect processes for clinical activities within an institution or its affiliated practices; however, with the advancement of telemedicine and telepharmacy, health care organizations may reassess their privileging procedures to

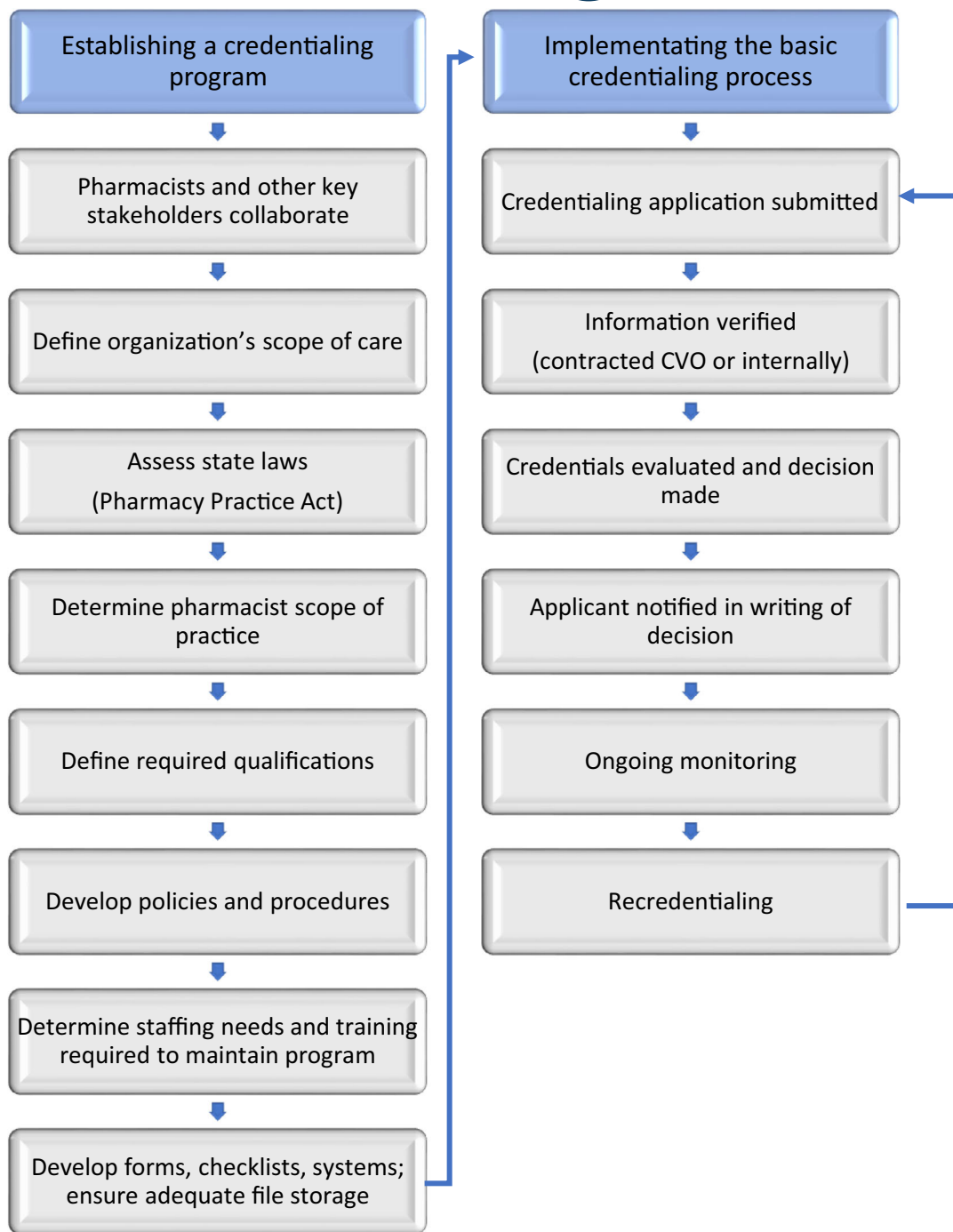


FIGURE 1 Establishing a credentialing program and implementing the basic credentialing process

accommodate these evolving practices. To this end, CMS, in conjunction with TJC, has developed guidelines such that institutions may request a practitioner using telemedicine to apply directly for privileges or through a “privileging by proxy” process.²³

7 | PROCESS FOR INITIAL PRIVILEGING

Clinical privileges are granted when three primary conditions are met: (a) the health care professional has demonstrated the competence to

deliver designated services, (b) the services are within both the individual's scope of practice and the institution's scope of services, and (c) the institution can support those services.¹¹ Usually, the individual initiates the request for privileging and completes the necessary forms provided by the privileging entity. Many institutions have committees to review the application (eg, Credentials Committee). Table 1 lists examples of credentials and other professional attestations that may be requested during the privileging process.

Although clinical pharmacists have successfully pursued the privileging process within their institutions since at least the 1990s,

an individual may be the first clinical pharmacist to seek privileging in his or her institution. In such situations, the application forms may lack criteria specific to pharmacists' clinical activities and scope of practice, which may be daunting to a pharmacist inexperienced with seeking clinical privileges. In addition, privileging documents may contain the term LIP, where legally allowed, for physicians, nurse practitioners, physician assistants, etc., whereas pharmacists seeking privileging may be categorized as allied health professionals or, to use a more contemporary term, other licensed or certified practitioners (OLCPs). The *Credentialing and Privileging File Review Resource* provides not only a checklist for potential privileging activities but also a comparison of criteria between LIPs and OLCPs, which the first-time applicant may find useful.²⁴

8 | REVIEW OF PRIVILEGES

Similar to credentialing processes, clinical privileging processes require clinical pharmacists to reapply for clinical privileges according to the frequency determined by the institution (eg, annually, biannually), and failure to provide the required documentation of competency within the designated time interval results in loss or denial of privileges. This process not only ensures that the requisite qualifications have been maintained, but also allows for review of any professional misconduct

TABLE 1 Examples of documents requested by the medical staff office (MSO)

Attestation of degree(s) relevant to the area of practice
Attestation of board certification(s) or any other credentials
Attestation of the fulfillment of continuing education requirements
Attestation of one's medical ability to perform patient care activities
Attestation of vaccination or immunity
BLS/ACLS (basic life support/advanced cardiac life support) certification
Institutional bylaws and updates
Code of conduct
Collaborative practice agreement (CPA)
Confidentiality/Health Insurance Portability and Accountability Act (HIPAA) policy statement
Evaluation by manager or supervisor
Disaster and inclement weather policy describing expectations of those with clinical privileges in the event of a disaster
Evidence of liability insurance
Attestation of professional liability claims
Institution-specific education and competencies such as emergency codes, infection control
Performance evaluation (submitted by supervising physician)
Registration with state prescription drug monitoring program
State license(s) in good standing (eg, registered pharmacist license and advanced practice license, when applicable)
Patient safety policies describing expectations for those with clinical privileges in various patient safety situations (eg, use of restraints)

or substandard care. Furthermore, during this reappointment process, expansion or modification of services may be evaluated. Finally, peer review is crucial in the reappointment process. When a pharmacist provides clinical services under a collaborative practice agreement (CPA) with a physician provider and is an employee of the health system's department of pharmacy, participation in the peer-review process by both professions may be required for the reappointment process. CPAs can vary widely from state to state and, in some states, CPAs may be between specific physicians and specific pharmacists, whereas in other states, they may be between the medical staff and the qualified pharmacist staff, which may affect how the peer-review process is enacted.

9 | MAINTENANCE OF PRIVILEGES

Maintenance of clinical privileges for the continuation of clinical pharmacists' services within the practice site is essential to ensure patient safety. Initially, institutions may employ a proctoring or performance monitoring period for newly privileged professionals in addition to the submission of required documentation. Over time, conditions external to an individual's clinical performance such as turnover in department leadership, changes in a department's mission, loss of department pharmacist staff, and departure of a supervising or collaborating physician may arise and present challenges to maintaining privileges. Aside from such challenges, the continuation of services created through privileging is incumbent on both the clinical pharmacist, who must maintain competence as defined by practice standards, and the institution, which must demonstrate its oversight of the privileging process.¹ Institutions use tools for best practices in the continuance of professional performance. One such tool is the ACCP Template for Evaluating a Clinical Pharmacist.²⁵ This template measures, evaluates, and documents a clinical pharmacist's performance over six core competency domains and can be used in any practice setting. The ACCP template is useful as an assessment tool for determining whether a clinical pharmacist meets predetermined performance criteria. Another tool is the Ongoing Professional Practice Evaluation (OPPE), together with the Focused Professional Practice Evaluation (FPPE), both of which are standards described in the Medical Staff chapter of TJC's *Comprehensive Accreditation Manual for Critical Access Hospitals*. Defined as "a document summary of ongoing data collected for the purpose of assessing a practitioner's clinical competence and professional behavior," the OPPE can be used for LIPs and OLCPs alike. Although TJC mandates the OPPE (and FPPE) process, it allows institutions to create criteria specific to the practitioner's scope of practice.²⁶⁻²⁸ Pharmacists at institutions such as Truman Medical Center (TMC) in Kansas City and The Johns Hopkins Hospital (JHH) in Maryland have collaborated with their privileging entity to create OPPE metrics specific to pharmacists' clinical services.¹²

10 | ORGANIZATIONAL COSTS

The costs incurred by an organization when developing a credentialing and privileging process can be daunting. For example, expenses are

TABLE 2 Barriers to credentialing and privileging

Barrier	Discussion	Potential Solution
Institution type	<ul style="list-style-type: none"> Organizational structure of an institution (large academic medical center vs small community hospital) <ul style="list-style-type: none"> Smaller institutions may not have the resources or infrastructure to manage the administrative aspects of Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) requirements Organizational funding for clinical pharmacist credentialing may differ depending on the type of institution 	<ul style="list-style-type: none"> Explore avenues to incorporate FPPE and OPPE processes for clinical pharmacists into established processes for other provider types Work with departmental and/or hospital finances to incorporate funding for credentialing into the department budget
Existing health care culture	<ul style="list-style-type: none"> Insufficient organizational support <ul style="list-style-type: none"> This often stems from limited knowledge of the benefits associated with credentialed and privileged clinical pharmacists, subsequently leading to a lack of recognition of clinical pharmacists as a credentialing and privileging entity Policy restrictions and hospital bylaws <ul style="list-style-type: none"> Institutional policies may prevent pharmacists from providing services via credentialing and privileging pathways Lack of standardized credentialing and privileging processes for clinical pharmacists <ul style="list-style-type: none"> No standard or accepted credentials for privileging have been established by national organizations to guide institutions on the appropriate and required credentials for privileging, nor is there a standardized pathway for institutions to obtain privileging for clinical pharmacists. This may contribute to a hesitancy within institutions to privilege pharmacists Concern for accountability <ul style="list-style-type: none"> The primary provider or "attending of record" may believe he or she will be held accountable for any adverse events that result from actions made by a privileged clinical pharmacist The clinical pharmacist may fear being held accountable for the associated consequences related to an adverse outcome in a patient 	<ul style="list-style-type: none"> Identify a multidisciplinary group of key individuals (physicians, hospital administrators, pharmacy administrators) who can serve as champions or partners in the credentialing and privileging process by influencing policy, supporting funding opportunities, and spreading recognition and knowledge of the benefits of clinical pharmacists as a privileging entity With the 2012 Centers for Medicare & Medicaid Services (CMS) ruling that modified its definition of medical staff to include non-physician practitioners such as physician assistants and clinical pharmacists as eligible candidates to perform all functions within their scope of practice and be reimbursed by CMS, hospitals may be more supportive of advancing the pharmacist's role and may override institutional policies that limit a pharmacist's scope of practice Create metrics to quantify the value of privileged clinical pharmacists. These metrics can focus on improved quality of care, cost-containment, improved resource use, and reduction in adverse events Collaborate with the legal department within each entity (eg, hospital) to better understand the privileged pharmacist-specific implications associated with an adverse event. Investigate institution-offered liability insurance, which may only protect the institution, and personal private liability insurance coverage
Information technology (IT) infrastructure	<ul style="list-style-type: none"> Monitoring systems (FPPEs, OPPEs): <ul style="list-style-type: none"> Institutions must have an electronic system that can facilitate the monitoring of initial and long-term credentialing and privileging Identification of credentialed and privileged pharmacists within the electronic medical administration record (eMAR) <ul style="list-style-type: none"> This will provide easy recognition of these clinical pharmacists and transparency to providers 	<ul style="list-style-type: none"> Seek assistance from other institutions that have a successful IT infrastructure for OPPE and FPPE requirements Use specialized functions within the eMAR upon order entry to identify privileged individuals. Block non-credentialed/privileged entities from performing certain activities within the eMAR
Provider group integration	<ul style="list-style-type: none"> Incomplete integration promotes systematic inefficiencies, potential duplicate work, and communication breakdown <ul style="list-style-type: none"> Integration may especially be hampered by a lack of clear delineation and communication of the role, responsibilities, and activities of the credentialed and privileged clinical pharmacist The quality of a clinical pharmacist's relationships within the health care team also influences the success or extent of integration 	<ul style="list-style-type: none"> Involve key stakeholders from the beginning of the credentialing and privileging process to cultivate both ownership of the initiative and the relationships necessary for full integration into the health care team Delineate clear roles, responsibilities, and activities emphasizing unique services that may enhance team functioning Discuss unique clinical pharmacist-provided services and the development of specific

(Continues)

TABLE 2 (Continued)

Barrier	Discussion	Potential Solution
	<ul style="list-style-type: none"> • Overlap in health care staff roles can create tension and impair communication <ul style="list-style-type: none"> ◦ This may arise from competition with other health care professions for budget funding and/or specific responsibilities. For example, some institutions exclusively use dietitians for management of nutrition services, though pharmacists are also trained to manage total parenteral nutrition 	<p>processes that may foster collaborative relationships</p>
State-specific legislation ^a	<ul style="list-style-type: none"> • State-specific legislation for credentialing and privileging may require inclusion of evidence-based protocols in the individual agreement, description of informed consent or opt-out provisions, liability insurance provisions, continuing education requirements, etc. For example, New York requires patient consent for all CDTM (collaborative drug therapy management) activities 	<ul style="list-style-type: none"> • State-specific legislation should be clarified early in the process • Developing working relationships with the state board may be helpful • Seek assistance from other successful programs in that specific state

^aInformation from: National Alliance of State Pharmacy Associations (NASPA). Key Elements for CPA Legislative and Regulatory Authority. Available at <https://naspa.us/resource/cpa-report/>. Accessed April 24, 2019.

associated with the personnel needed to oversee the program, the technology used in the program, and the verification of health care provider credentials. Depending on the organization or CVO offering the credentialing service, the health care provider seeking to be credentialed may need to pay a fee. Use of existing credentialing/privileging pathways for medical staff or other providers is highly recommended to control costs. If the organization has no established process, outside resources such as CVOs may be helpful.

Fees may be associated with attaining and maintaining clinical privileges within a hospital, health care system, or affiliated practice and may vary widely. Factors involved in fee schedules may include the local cost of living, size of the health care institution (and its professional staff), initial or renewal application status, and costs incurred by the MSO or other credentialing entity within the organization. Fees are expected to be paid at the time of the initiation and renewal of privileges, or at a set time determined by the institution.

11 | BEST PRACTICES

Clinical pharmacist participation in team-based care can result in decreased hospital stays, reduced number of 30-day hospital readmissions, increased use of evidence-based therapies, improved quality performance metrics, enhanced medication adherence, and reduced total costs of care.²⁹⁻³¹ However, despite evidence supporting improved quality of care with clinical pharmacist participation on the team, there remains a need to document that the clinical pharmacist's competence and experience attest to his or her ability to carry out specific clinical responsibilities. Existing models of credentialing and privileging processes may serve as useful examples.

Within health-systems practice, the VA and the USPHS Indian Health Service have established programs allowing pharmacists to take ownership of certain clinical services. Organizations such as

TMC, JHH, and The Ohio State University Wexner Medical Center (OSUWMC) have published on approaches to clinical privileging within their organizations.¹² OSUWMC has established core and optional privileges to promote competence and advanced practice, collaborative care, and accountability for its clinical pharmacy services. OSUWMC has also established criteria for core and optional privileges and semiannual practice evaluations as well as competency tests. At TMC, all pharmacists complete the credentialing and privileging process, which allows them to engage in medication therapy protocols (the state's terminology for CPAs) approved by the medical executive committee. TMC uses a core, criteria-based privilege list, rather than an approach in which individual privileges are requested and monitored, and a focused competency program to measure performance. Within JHH, pharmacists with advanced training can engage in CPAs with providers in accordance with the state's laws and regulations. These agreements allow the clinical pharmacist to modify, change, continue, or discontinue therapy within a disease- or condition-specific protocol without requiring an oral order or co-signature. Pharmacists performing these activities are privileged through the organization's credentialing and privileging process (which involves privileging through the medical department they work with most closely, as well as department chair approval).

Credentialing and privileging processes within hospital-based clinics are typically under the protocol provided by the parent hospital or health system. The Department of Defense (DoD), most notably Army pharmacy, as well as the VA and the Indian Health Service have historically served as models where clinical pharmacists practice direct patient care in the ambulatory care setting. Appropriately credentialed clinical pharmacists in the DoD and VA have the authority to initiate, titrate, and discontinue medication(s) as well as order laboratory tests to monitor the safety and efficacy of medication use. Federal laws do not regulate health professionals and therefore do not dictate the specific patient care services that pharmacists are authorized to provide.

TABLE 3 Publications and Resources

Citation	Practice site	Requirements	Scope of services	Outcomes/value	Barriers
Claxton 2006 ^a	Ambulatory specialty clinics (specifically anticoagulation, pain management, and anticonvulsant clinics)	Each clinic role includes specific privileges; pharmacist must demonstrate competence through an application process	Pharmacists working in each specialty area make individualized changes to the patient's medication therapies, including appropriate monitoring	Pharmacists provide positive feedback regarding demonstration of pharmacy competence	Complicated and lengthy application and training processes, staff education regarding the credentialing process
Dager 2011 ^b	Inpatient intensive care unit	Required credentials should be tailored to the desired clinical services, ranging from fundamental levels to an optimal level, including residency training, board certification, and ACLS (Advanced Cardiac Life Support) certification	Various models are discussed, ranging from fundamental services to more advanced specialty services	Activities performed should be documented to demonstrate clinical effectiveness, cost, diversity, and overall outcomes	Lack of efficiency in the documentation and verification of credentialing, lack of validation for currently available credentials, need for continued competency assessment
McFarland 2018 ^c	System-wide within the Veterans Affairs (VA) health system	Initial competency assessment (including, but not limited to, completion of residency training, board certification, documented clinical experience in the requested practice area, and ongoing competency assessment forms)	Credentialed practitioners have the authority to prescribe and monitor various diseases as defined in the VA handbook. Pharmacist mentorship programs are also an essential element of the credentialing process	Developing a system-wide credentialing process allows common elements of practice to be well defined and to serve as a foundation on which to continue building pharmacy services	Stringent and vast oversight process necessitating specific processes to ensure all required elements are met
McBane 2015 ^d	All practice settings in which a relationship exists between pharmacist, provider, and patient	Clinical pharmacists should have completed residency training or equivalent clinical experience AND be appropriately privileged	CMM (comprehensive medication management) and CDTM (collaborative drug therapy management)	Economic studies have estimated the benefit-cost ratio of clinical pharmacy services to be anywhere from 1.05:1 to 25.95:1	Variations in state regulations, challenges associated with billing for services
Merrigan 2002 ^e	Hospital setting	Clinical pharmacists should have completed residency training or have demonstrated clinical experience in delivery of direct patient care	Various models are presented, including treating hypertension and providing anticoagulation and other services	Data are presented from studies evaluating the effectiveness of pharmacists functioning as prescribers, and these data indicate that pharmacists can do so effectively	Corporate and hospital liabilities, as well as potential liability of the supervising provider
Merten 2013 ^f	Hospital setting and/or ambulatory clinic for hematopoietic stem cell transplant recipients	Completion of oncology pharmacy residency, board certification in oncology pharmacy (BCOP), and institution-specific training	Collaborative practice for the management of medication therapy during and after allogeneic and autologous stem cell transplantation	Improves patient clinical outcomes, which can be represented by survival, hospitalization, graft-vs-host disease or other complications, or surrogate markers	Additional strain on staffing and training requirements, determining appropriate metrics to quantify value

(Continues)

TABLE 3 (Continued)

Citation	Practice site	Requirements	Scope of services	Outcomes/value	Barriers
Philip 2013 ^a	Acute and ambulatory care settings	Suggestions for credentialing requirements include residency training, board certification, clinical experience, and competency examinations	After diagnosis by the physician, the pharmacist takes the lead in selecting medication regimen, writing prescriptions, and monitoring	Improves efficiency of pharmacists and physicians, ensures a high level of competence of pharmacists, and improves patient outcomes	Interdisciplinary colleagues adapting to the changing role of pharmacists, justifying value as a clinical care department rather than an ancillary service, inability to bill for direct patient care services
Jordan 2016 ^b	Hospital setting - several models are discussed, including the VA, the TMC health care system in Missouri, the JHH in Maryland, and the OSUWMC in Ohio	Completion of residency training, board certification, or equivalent program (as defined by individual state boards of pharmacy)	The models described in this article cover a wide variety of services, including general and specialty pharmacy services	Improves patient access to care and clinical services while allowing pharmacists to practice at the top of their licensure	Navigating state regulations, identifying metrics and evaluation, staff education, and administrative costs associated with credentialing

^aClaxton KL, Wojtal P. Design and implementation of a credentialing and privileging model for ambulatory care pharmacists. *Am J Health Syst Pharm* 2006;63:1627-32.

^bDager W, Bolesta S, Brophy G, et al. An opinion paper outlining recommendations for training, credentialing, and documenting and justifying critical care pharmacy services. *Pharmacotherapy* 2011;31:829.

^cMcFarland MS, Groppi J, Ourth H, et al. Establishing a standardized clinical pharmacy practice model within the Veterans Health Administration: evolution of the credentialing and professional practice evaluation process. *J Am Coll Clin Pharm* 2018;1:113-8.

^dMcBane SE, Dopp AL, Abe A, et al. Collaborative drug therapy management and comprehensive medication management - 2015. *Pharmacotherapy* 2015;35:e39-e50.

^eMerrigan D. Internal approach to competency-based credentialing for hospital clinical pharmacists. *Am J Health Syst Pharm* 2002;59:552-8.

^fMerten JA, Shapiro JF, Gulbis AM, et al. Utilization of collaborative practice agreements between physicians and pharmacists as a mechanism to increase capacity to care for hematopoietic stem cell transplant recipients. *Biol Blood Marrow Transplant* 2013;19:509-18.

^gPhilip B, Weber RJ. Enhancing pharmacy practice models through pharmacists' privileging. *Hosp Pharm* 2013;48:160-5.

^hJordan TA, Hennenfent JA, Lewin JA III, et al. Elevating pharmacists' scope of practice through a health-system clinical privileging process. *Am J Health Syst Pharm* 2016;73:1395-405.

State statutes and regulations define the pharmacist's scope of practice, and these have historically been conservative. Army Regulation 40 to 68 states that to be a clinical pharmacist, a qualified individual must have a degree, "clinical pharmacy experience/training," and a state license to practice pharmacy and may possess certification by the Board of Pharmacy Specialties.³² The VA's clinical guidelines, titled the VA Pharmacists Qualification Standards, VA Handbook 5005, require similar credentials for clinical pharmacists.³³ VHA Handbook 1108.11 outlines the clinical pharmacist's scope of practice.³⁴ The VA recommends an optional mentoring program for newly employed clinical pharmacists with more established colleagues. Neither organization permits clinical pharmacists to diagnose or prescribe controlled substances. Finally, prescribing privileges and ordering of laboratory tests for the DoD and the VA are only recognized within the confines of the facility and not within civilian organizations.

Although the examples described are within health systems and hospital-based clinics, it remains essential that personnel in any setting where clinical pharmacists provide direct patient care adopt credentialing and privileging processes. This includes, but is not limited to, ambulatory clinics, community-based pharmacies, and long-term care facilities.

12 | BARRIERS

Consistent use of credentialing and privileging for clinical pharmacists across health care settings can improve patient care outcomes and influence efficient and effective use of health care resources. The scaling of these processes, however, can be challenging because of limitations such as the need for substantial changes in the existing health care culture and the lack of resources from a management and infrastructure perspective. Table 2 describes specific barriers to the credentialing and privileging process and identifies potential strategies to overcome these challenges.

13 | RESOURCES

A precise timeline for establishing clinical pharmacist privileging and credentialing within an institution may vary depending on the institution and its practice requirements. Many previous publications offer considerations and guidance for establishing such a timeline.^{9,11,15,18}

Table 3 identifies publications and resources that describe successful models, which may be helpful in establishing and maintaining institutional standards for clinical pharmacist privileging and credentialing.

14 | CONCLUSION

As the pharmacy profession continues to evolve and clinical pharmacists provide an increasing range of patient care services in a variety of settings, it is important that credentialing and privileging processes be consistently implemented. Although the concepts of credentialing

and privileging are not new to clinical pharmacy, the credentialing and privileging of a clinical pharmacist to provide direct patient care services may be new in many practice settings. In addition, implementation of and approaches to performing credentialing and privileging may vary widely depending on the practice setting. This white paper provides a reference and guide for managers, administrators, and clinicians who are developing credentialing and privileging pathways for clinical pharmacists.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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