

Health Care Facility Licensure and Enrollment:

Establishing a Cohesive Program to Reduce
Financial and Organizational Losses

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Universe of Licensure and Enrollment

In establishing a licensure/enrollment program, the first step is to identify the universe of licensure applicable to the organization and practitioners. The universe will be determined by the specific scope of professional services, departments and operations maintained by the provider; however, the following categories serve as a reliable framework for identifying the specific licensure needs of most organizations:

Business and Organizational Permits and Registrations

e.g., state entity and d/b/a registrations, IRS tax identification number, IRS tax classification approvals, state sales/franchise tax registrations

01

Individual Practitioner Licensure

e.g., physician licensure with medical boards, nursing licensure with nursing boards, technician certifications

02

Enrollments in Government and Private Payer Programs

e.g., National Provider Identifier (NPI), Medicare, Medicaid, TRICARE, third party payers

03

Clinical Operations Licensure

Pharmacy

e.g., Board of Pharmacy permit, DEA and state-controlled substance registrations, weights & measures permits

Laboratory

e.g., CLIA waiver/certificate, state lab licensing, College of American Pathology accreditation

Radiation

e.g., state x-ray machine registration, radioactive material license, radioactive laser registration, FDA mammography certification

04

Physical Plant Licensure

e.g., Certificates of Occupancy, biomedical waste permits, food services licensure

07

Mobile Operations Licensure

e.g., ambulance license, FAA registrations (air operations), FCC call signs

06

Accreditations

e.g., The Joint Commission, Healthcare Facilities Accreditation Program, American College of Radiology, College of American Pathologists

05

Over the past several years, we have heard a consistent and increasingly frequent lament from our health care facility clients and colleagues: our organization is losing time and money as a result of issues in managing the licenses, certifications, accreditations and enrollments required of our organization and practitioners. Errors and inefficiencies in this area often lead to lost reimbursement, administrative penalties, terminations and suspensions, lost practice days, and organizational disorder. A provider organization's legal counsel is uniquely situated to reduce

these losses and inefficiencies by implementing an organized licensure/enrollment program that proactively manages this area. This article will discuss implementation of an effective licensure/enrollment program, including: (i) identification of the universe of licensure applicable to a health care facility; (ii) review of the elements of an effective licensure program; (iii) recommendations for the maintenance of a licensure program; and (iv) review of the impact a licensure program has in a change of ownership.

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Elements of the Program

To many, the sheer number and complexity of licensure and the corresponding regulatory requirements can be overwhelming. As counsel, we are uniquely situated to recognize the commonality in these disparate categories of licensure. We can bring order and efficiency to this area by instituting an organized licensure program that (i) establishes centralized leadership; (ii) collaborates with a supporting team; (iii) maintains ownership of core organizational information; and (iv) develops an internal tool to effectively maintain each license and enrollment.

When it comes to licensure and provider enrollment, an organization is infinitely stronger with an individual leader and singular point of contact who is responsible for the licensure program. Problems often arise when a provider's different departments operate independently and no one person or group has ownership over the entire program. Often, fractionalized leadership leads to inaccuracy and inconsistency on the various licenses and certifications because the individuals managing the enrollments and renewals are not always knowledgeable about the entity's legal corporate structure or governance, or they are unfamiliar with the broad range of licensure and regulatory requirements applicable to their organization. Further, when an accreditation is threatened by revocation, the company or one of its employees often comes under investigation. In other instances, the company may be in the midst of being acquired. In either case, it is beneficial to have an established leader who can confidently answer inquiries about the licensure, certification, provider enrollments, and corporate structure, as well as direct necessary filings and communications with governing agencies as a result of the investigation or acquisition. The individual serving as program leader may vary among organizations (e.g., administrator, compliance officer, practice manager), but the entity's legal counsel is most effective in this role.

The licensure and enrollment process frequently involves regulatory considerations such as the following:

- How is the hospital's new outpatient department enrolled in Medicare based on its provider-based status?
- Does the off-campus ASC require separate facility licensure?
- What type of adverse legal actions must be disclosed under the Medicaid enrollment?

It is important that the individual responsible for addressing issues of this nature be able to do so accurately and efficiently. Directing the course for the organization on these licensure and provider enrollment issues can be pivotal to the ultimate success or failure of a particular venture, and inaccuracies in these considerations can be costly for a provider. The program leader must have a clear understanding of the organization's legal and ownership structure—as well as sufficient status within the organization to have a seat at the table at the outset—as acquisition and development issues are considered. Finally, the program leader must be in a position to promptly address both major and minor licensing and enrollment problems. This requires that all licensure information be accessible to the program leader, who will also need immediate access to the organization's executive team, practitioners, and department heads in order to implement immediate corrective steps. The availability of the attorney-client privilege and other such protections with respect to communications between the entity and its legal counsel may also prove beneficial in these circumstances, such as, for example, in the case of a provider appealing an agency enforcement action through administrative hearing.

Of necessity, the licensure program leader will depend heavily upon a team of facility personnel and departments to effectively operate the program. The provider's reimbursement and revenue cycle departments are integral in understanding what enrollments and payer contracts an organization requires, and in resolving claim disputes with those payers. A facility's clinical departments dictate the scope of equipment, service, and practitioner licensure that is required to provide services. The compliance department can be useful in an organization's reporting obligations, specifically in the area of adverse legal actions. Finally, the program leader works hand in hand with the provider's executive team to authorize licensing activities and structure the appropriate licensure for the organization's transactions and day-to-day operations.

One of the most practical benefits a licensure program can provide is maintaining an accurate and easy-to-access record of the information essential to an organization and its providers. Whether the organization is responding to due diligence requests or renewing its hospital license, the information must be consistent and clearly

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conveyed. To begin with, the program must be responsible for accurately conveying the legal entity structure (e.g., corporation, partnership, LLC, etc.), the chain of ownership, and the makeup of the company's managing officers and directors. This information is foundational. It is required in everything from a provider's Board of Pharmacy permit to its Medicare enrollments. Further, the program must maintain the history of all adverse legal actions for each of its owners, officers, directors and administrators. This requires close collaboration with the provider's compliance and legal teams. The licensure team should at all times be apprised of the organization's beds and services, practice locations, and clinical directors. Finally, the licensure leader should serve as the authority on the organizational documents used in agency filings. Almost everyone has experienced the confusion and wasted time of searching for the most current copy of the hospital's license or IRS W-9 form.

Toward this end, the licensure program should maintain a repository of the following documents that will make interaction with governing agencies significantly more efficient:

- **Company's Organizing Documents**
(Articles of Organization, Operating Agreement, Corporate Resolutions, Incumbency Certificates)
- **IRS Documents** (W-9 Form, CP575, Determinations of disregarded entity status)
- **Physician/Mid-Levels Roster**
- **Current Copies of Facility Licensure**
- **Transaction Documents** (Bills of Sale, Purchase Agreements)

In order to bring all these program elements together, the licensure program should create a tool that tracks the organization's licensure and the key information necessary to maintain it. The form of this tool can vary (e.g., Excel spreadsheet or Google doc), so long as it is in a format that your team can easily use and share with other members of the organization. At the very least, the tool should capture the type of license and license number, the applicable licensing agency and agency contact, the effective date of the license/enrollment, upcoming renewal or revalidation dates, and reporting history. This tool will be the first thing the program leader consults when the facility is undergoing a change of ownership, closing down a department, or updating its Board of Directors. It will also serve as a visual representation of the commonality in the universe of licensure and should reduce the confusion and uncertainty that is so common in this arena.

Maintenance

Issues that providers experience in licensure maintenance are rarely the result of bad actors or bad intentions; instead, they typically arise from simple mistakes and failures in communication. An organized licensure program must timely address regulatory reporting and requests from governing agencies by asking: what needs to be reported, when does it need to be reported, and how does it need to be reported?

Serious consequences may flow from what might, in another context, be deemed a "footfault" or scrivener's error

in completing a form. In a recent HHS Department Appeals Board decision, an administrative law judge upheld CMS's decision to revoke the Medicare provider enrollment and billing privileges of Dr. Fares F. Yasin.¹ Dr. Yasin was not found to have committed fraud or engaged in criminal activity. Instead, his Medicare billing privileges were revoked due to a failure to notify CMS within 30 days of a change in his practice location.² His medical practice had submitted a CMS 855I application notifying CMS of a new practice location for the enrollment, but failed to correctly remove a terminated practice location.³ As a result, his billing privileges were revoked and he was barred from re-enrollment in the program for a period of two years.⁴

It is not uncommon for providers to experience difficulties in this area. Frequently, such difficulties are the result of

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a provider delegating responsibility for the maintenance of a practice's licensure (e.g., reporting, renewal, updates, etc.) to an employee lacking the tools or management skills to effectively manage the program. Each license and enrollment is subject to regulations with exacting reporting and application requirements. Dr. Yasin's case demonstrates that even small errors in the timing or form of a filing can have serious consequences, and that CMS (among other agencies) may strictly enforce regulatory requirements governing these maintenance actions. In a similar case, a HHS administrative law judge asserted that "The [Medicare] contractors who administer the program on a day-to-day basis are confronted with immense amounts of information and are responsible for processing and organizing that information . . . it is essential that they receive relevant information in a routinized way."⁵

The precise rules regarding license update and reportable events will vary among agencies. An effective, centralized program leader will have the knowledge and understanding required to be aware of certain hallmark events that consistently require reporting regardless of the agency: changes in ownership, location, practice name, and corporate officers; adverse legal events experienced by the organization,

A health care provider organization can significantly reduce losses in the licensure area by instituting an organized licensure program.

providers or officers; the addition of new providers or services; and changes in payment information affecting payer enrollments. It is helpful to include regulatory citations in the program's licensure tool as a quick reference to determine exactly what information must be reported to each agency. This is especially relevant when reporting adverse legal events. For example, in Texas, if a managing employee of one of our provider clients has experienced a legal issue, our disclosure obligations may vary depending on the entity's licensure. Under Medicare enrollments, the pivotal question is whether a managing employee was convicted of certain federal or state felony or misdemeanor offenses.⁶ Conversely, the organization may be subject to pharmacy reporting requirements in the event there are *any* actions related to a crime (e.g., arrests, charges, pleadings, convictions).⁷ A licensure program leader must be aware of—and be able to carefully evaluate—each agency's reporting requirements and apply them to the facts of a particular situation.

A licensure program leader must also be diligent in complying with timing and form requirements in maintenance activities. The precise timing of a filing, or the form or letter used to notify an agency may seem inconsequential to those who are not in leadership roles in an organization, with the potential downstream ramifications not fully appreciated. To illustrate, a health system client recently experienced a clinical issue at one of its off-site outpatient clinics resulting in a revocation notice from one of its accrediting bodies. The site's accreditation would have been revoked if the provider had not timely submitted a written notice of appeal. The client did not have a licensure program and process in place, and the revocation notice remained at the off-site clinic without being forwarded to client's leadership. The on-site clinical leaders, unfamiliar with the appellate process, focused solely on corrective actions with no attention to an appeal. A request for appeal was not submitted until weeks later once the revocation notice had finally been submitted to the organization's leadership and made its way to counsel. By that time, the appeal period had expired and the clinic's accreditation was revoked.

Change of Ownership or “CHOW”

Finally, the licensure program representative is a necessary member of an organization's transactional team as it navigates the “change of ownership” (CHOW) process. A health care provider's licenses and enrollments will significantly impact the structure and timing of a transaction, and the leader of the licensure program is well suited to direct and implement the CHOW process.

A primary consideration in health care transactions is determining how historic liabilities associated with certain licenses and enrollments will be allocated among the parties to the transaction. These determinations are heavily influenced by how the governing regulations of a certain license or enrollment defines a change of ownership. Federal regulations governing the Medicare and Medicaid programs, which instruct many state facility licensing bodies, define a “change of ownership” as: the removal, addition or substitution of a partner in a partnership, an asset purchase where the purchase accepts transfer of the seller's provider agreement, a merger/consolidation where the merger or consolidation of two or more corporate entities results in the creation of a new corporation, or the lease of all or part of a provider facility.⁸ Understanding how CHOW is defined is important because a change of ownership results in automatic assignment of the provider agreement to the new owner and a formal change of ownership process with CMS and the state Medicaid program.⁹ The transaction documents must therefore specifically delineate responsibility for licensure/enrollment liabilities, and the parties must coordinate responsibility for a prolonged transfer process.

Alternatively, CMS and most state facility licensing bodies will not require a license/provider agreement transfer and formal change of ownership process for a stock or membership interest transfer with no change to the provider's tax identification number, a merger where the provider corporation is the surviving entity, or an asset purchase in which the purchase does not accept assignment of the provider agreement or license.¹⁰ The licensure program must work closely with the transaction team to instruct on how the organization's licenses and enrollments will influence the structure of a transaction.

Regulatory approvals associated with a license or enrollment will also impact the *timing* of a transaction. Our clients in Texas are fortunately spared from any form of certificate of need (CON) process. However, thirty-seven states have instituted some form of CON law, and obtaining CON approval must be given ultimate priority as it is often one of the most time consuming components of a hospital licensure process.¹¹ A facility's pharmacy licensure also must be given priority in a change of ownership. The permits and registrations required for a pharmacy are obtained sequentially; the pharmacy must obtain its state permit before completing any state or federal controlled substance registrations. As a result, the pharmacy licensure process can continue months past the effective date of a transaction. In this situation, a licensure program leader can recommend that the parties implement a power of attorney to let the surviving entity continue use of the former provider's pharmacy licensure while the CHOW is being completed.

Lastly, the Medicare and Medicaid CHOW process will often extend months beyond a transaction date, requiring the parties to institute a process for allocating reimbursement for pre- and post-transaction services. A licensure program can help its organization by taking advantage of CMS's early filing time-lines, state Medicaid programs that permit simultaneous Medicare/Medicaid CHOW applications, and timely responding to all agency requests for additional information.

Finally, the licensure program must take center stage in the implementation of a CHOW process. As soon as our clients permit, our practice is to submit notice letters to every applicable licensing agency making them aware of the anticipated timing and structure of the transaction, and requesting their input on the CHOW process. We do this for several reasons. First, it immediately establishes a line of communication with the agency. Second, it serves as a potential backstop for any agency claiming that it was not notified of the change of ownership. Finally, we often learn of subtle nuances an agency may employ in evaluating a CHOW that are not found in the governing regulations. An organized licensure program can provide an organization with confidence that the transfer of its licensure will not impede operations or delay a transaction. The CHOW process should be directed by the program leader, be implemented in consultation with the licensure support team, and utilize the program's licensure tool in completing the applicable filings and submissions.

Conclusion

A health care provider organization can significantly reduce losses in the licensure area by instituting an organized licensure program. The provider's legal counsel is in a unique position to lead in this area, supported by key departments and personnel within the organization. The presence of a licensure program can create continuity in a fragmented practice area and bring efficiency to the acquisition, maintenance, and transfer of licenses and enrollments. **C**

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Thanks go out to the leaders of the In-House Counsel Practice Group for sponsoring this feature: **Robert Andrew Gerberry**, Summa Health System, Akron, OH (Chair); **Tizgel K. S. High**, LifePoint Health, Brentwood, TN, (Vice Chair—Publications); **Aletheia Lawry**, League City, TX (Vice Chair—Strategic Planning and Special Projects); **Terri Wayne Meldrum**, OhioHealth, Columbus, OH (Vice Chair—Membership); **Kimberly E. Peery**, Sutter Health, Emeryville, CA (Vice Chair—Research & Website); **Sarah E. Swank**, South Pasadena, CA (Vice Chair—Educational Programs); **Brian A. White**, Office of the General Counsel UConn Health, Farmington, CT (Social Media Coordinator). For more information about the In-House Counsel Practice Group, visit www.healthlawyers.org/PGs. Follow them on Twitter @AHLA_In_House.

Endnotes

- 1 Fares F. Yasin, M.D., DAB No. CR4425 (2015).
- 2 42 C.F.R. § 424.516(d)(1)(iii).
- 3 Fares F. Yasin, M.D., DAB No. CR4425, at 7 (2015).
- 4 *Id.*, at 11.
- 5 *Viora Home Health*, DAB No. CR4369 (2015).
- 6 Final Adverse Legal Action, 42 C.F.R. § 424.502.
- 7 22 T.A.C. 291.1(b); Texas Board of Pharmacy Form LIC-021 (1/18), available at www.pharmacy.texas.gov/files_pdf/LIC-021.pdf.
- 8 42 C.F.R. § 489.18(a).
- 9 *Id.*, at (c).
- 10 *Id.*, at (a)(3). Several Texas facility licensing agencies follow CMS's exclusion of "stock transfers" from the definition of "change of ownership": Texas DSHS hospital license, 25 T.A.C. § 133.24(a); Texas DSHS ambulatory surgical center license, 25 T.A.C. § 135.2(9); Texas DSHS freestanding emergency medical center license, 25 T.A.C. § 131.2(8); and Texas HHS home health license, 40 T.A.C. § 97.2(25).
- 11 Richard Cauchi and Ashley Noble, *CON-Certificate of Need State Laws*, National Conference of State Legislatures (Aug. 25, 2016), available at www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last visited June 14, 2018).