Benefits of developing a collaborative, outcomes-based specialty pharmacy program

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Purpose. The benefits of developing a collaborative, outcomes-based specialty pharmacy program are described.

Summary. With the implementation of risk-based payment models and the rapid growth of specialty pharmacy spend, opportunities exist to establish collaborative and outcomes-focused specialty pharmacy contracts and related programs with regional third-party payers. University of Wisconsin (UW) Health and Unity Health Plans Insurance Corporation have established a contract that sets standards for patient management, pharmacist training and education, electronic medical record documentation, and prescription fulfillment for patients receiving specialty pharmaceuticals. Reporting on metrics of compliance, persistence, and outcomes relative to published benchmarks is required annually. While the contract defines patients by the traditional metric of specialty medication use and includes reimbursement for dispensing activities, it differentiates itself by establishing core services and longitudinal practice expectations for patient care rather than focusing on reimbursement for prescription fulfillment. While it focuses on specialty pharmacy practice, the contract provides an ancillary benefit to all patients using UW Health pharmacies by elevating ambulatory care pharmacy practice standards and improving the patient care process.

Conclusion. The collaborative development of practice standards, service requirements, and patient management protocols offers the rapid elevation of specialty pharmacy services, which provides significant differentiation within the highly competitive specialty pharmacy and third-party payer marketplaces.

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With the establishment of payment reform and at-risk payment models by the Centers for Medicare and Medicaid Services, health-system providers are incentivized to take ownership for specialty patient management and therapy outcomes. Pay-for-performance reimbursement arrangements are being created whereby health-system providers assume financial risk for the quality and cost of care being provided to patients. In these models, payment may be recouped or sequestered based on health-system performance for defined quality metrics. Due to this risk of decreased or lost reimbursement, health systems have increased their focus on the implementation of specialty pharmacy services, services that are complementary to the medical specialty services provided within their institutions.

As a result, there is a significant opportunity for health-system–based specialty pharmacies to coestablish outcomes-focused specialty pharmacy programs with payers. This not only reduces the inappropriate use of specialty medications within the health plan spend but, more importantly, improves the health outcomes associated with specialty medication use and reduces downstream medical costs related to the respective disease. This relationship between payer and
pharmacy provider has the potential to increase the services provided to the health plan member, retain funds within the health system that would otherwise be paid to external specialty pharmacy vendors, and elevate the practice level of the health system’s specialty pharmacy program.

Despite the importance of specialty pharmacy to health systems, there are minimal data or literature to aid health systems in benchmarking or sharing best practices. This is likely due to the rapid evolution of specialty pharmacy services in contrast to the chronic nature of specialty disease states and associated changes in patient outcomes. As a result, it is difficult to assess the total cost of care (combined medical and pharmacy expenses), optimal sites of care, and outcomes-based therapy measures. This ultimately affects the ability for health systems to reinforce and elevate the role of the pharmacist as an integral member of the interdisciplinary team in the care of specialty patients.

**Background**

Formed in 1994, Unity Health Plans Insurance Corporation (Unity), an affiliate of University of Wisconsin (UW) Health, provides community-based managed care products and services to 175,000 members throughout 21 counties in south central Wisconsin. Approximately half of these members have prescription medication benefit coverage with Unity. Unity focuses on community-based healthcare and direct access to leading medical centers.

UW Health is a tertiary care academic health system consisting of the healthcare entities of UW–Madison, the UW Medical Foundation, UW Hospital and Clinics, and the UW School of Medicine and Public Health. UW Health operates a significant ambulatory care clinic enterprise that includes specialty practices in neurology, gastroenterology, transplant medicine, rheumatology, dermatology, pulmonology, infectious diseases, and cancer care.

**KEY POINTS**

- A collaborative specialty management contract should be outcomes focused and elevate care management for patients treated with specialty pharmaceuticals.
- Elevation of standards related to specialty pharmacy training and education should be a core component of specialty pharmacy programs.
- Specialty pharmacy contracts should be outcomes focused rather than medication focused to allow for contract expansion.
- Leveraging the EMR for documentation represents a significant opportunity for improving the visibility of documentation, pharmacist interventions, and communication with providers regarding therapeutic outcomes.

UW Health also operates a health-system–owned ambulatory care pharmacy network at 14 locations throughout the Madison metropolitan area. All pharmacies specialize in personalized patient medication management and provide advanced services such as comprehensive medication evaluation and refill synchronization activities and no-cost delivery of pharmaceuticals. In addition, a medication prior-authorization service within the pharmacy department coordinates benefit investigation, prior-authorization initiation, refill reminders, and copayment assistance investigation for clinic-administered specialty and nonspecialty medications. The primary drivers of specialty pharmacy growth at UW Health have included negotiations of specialty pharmacy contracts (such as with Unity), close collaboration with the University HealthSystem Consortium, and direct access to specialists with expertise in the management of chronic diseases.

The early focus of the specialty programs was to improve clinic relationships with UW Health pharmacists while working to implement supportive programs for patients and payers. This relationship has evolved over time to take a more progressive focus on leveraging data to demonstrate improvements in patient outcomes and target interventions related to compliance, persistence with intended therapy, and meaningful therapy endpoints. This focus on collaboration and quality of pharmaceutical care has led to additional third-party contracting opportunities to support additional patients, third-party payers, and therapeutic areas.

**Program development**

Unity implemented its first specialty pharmacy network in January 2005, with a focus on value, defined as improvement in patient therapeutic outcomes and incremental increases in medication cost. The program also included a commitment to using local community-based pharmacy providers. Product selection for inclusion in the specialty pharmacy network began with traditional specialty drugs, which are often designated as high-cost, injectable products including growth hormone analogs (somatropin), disease-modifying therapies for multiple sclerosis, and biological-response modifiers for rheumatological disorders and inflammatory bowel disease.

A further revision to the contractual requirements in 2013 sought to maximize the value achieved through the investment in high-cost medications and the documentation of improved patient outcomes for plan members by establishing specialty network requirements. The new requirements specified that participating pharmacies must (1) review current clinical information in the medical record as a routine part of patient care when dispensing specialty medications, (2) develop standards for pharmacist train-
Pharmacist training and credentialing

Due to the rapid expansion of drug discovery, the variability of delivery devices, and the small patient populations requiring specialty pharmaceuticals, UW Health identified a need for improving pharmacist knowledge of these specialty products and overall patient management. With the implementation of the UW Health–Unity specialty services contract, UW Health became contractually obligated to develop disease- and medication-specific training programs to develop pharmacist expertise with the medications being managed under the Unity specialty pharmacy contract. Staff training is required annually and must be inclusive of a hands-on specialty medication device training session in addition to computer-based training modules on the management of specialty disease states.

During the hands-on training, the ambulatory care pharmacists are educated about the unique medication delivery devices available through the specialty pharmacy program. Training is provided in groups of three to five, with all ambulatory care pharmacists required to attend and demonstrate proficiency with each device. Individual sessions are also held for staff who require additional training or are unable to attend the group sessions.

Pharmacists involved in providing direct care to patients enrolled in the specialty pharmacy program are required to be board certified in their area of practice. This requirement closely matched an overall UW Health pharmacy department focus on staff development and certification, where all pharmacists who spend more than 50% of their time in direct patient care are required to undergo an approved and vetted certification program that is appropriate based on their area of practice. As the number of certifications specific to specialty pharmacy is limited, pharmacists were given the opportunity to choose the certification that met the UW Health pharmacy department guidelines. Through the certification-vetting process, it was determined that the board-certified oncology pharmacist, board-certified ambulatory care pharmacist, and certified specialty pharmacist programs were acceptable for specialty pharmacy staff.

EMR access and documentation

The ability to access EMRs for patients represents an opportunity to improve specialty patient care. The ability to access and review patients’ laboratory test results, medication profile, and notes from prior clinic visits and telephone encounters allows pharmacists to better assess patients’ response to therapy and triage patients back to the clinic for therapy evaluation.

In addition to standardized patient profile reviews, requirements related to the ability to document the pharmacist encounter within the EMR to improve coordination of care and provider visibility of specialty pharmacy services were included in the specialty pharmacy contract. To meet these requirements, collaboration with UW Health’s EMR vendor was necessary to identify tools available to complete EMR-based documentation of specialty patient care. While it was determined that a pathway could be created for documentation, no standardized form or document existed within the EMR. As a result, significant effort was required by the UW Health pharmacy informatics team to evaluate options and create documentation tools that generate a specialty pharmacy note in the EMR that is visible to all care providers. A standardized dictation-formatted note within the EMR was created. This note is formatted identically to other provider notes, contains discrete and reportable data elements, is fully visible to all care providers, and can be completed in real-time by frontline pharmacy staff members.

Documentation of patient care activities

The specialty services contract requires the documentation of all activities related to patient assessment, laboratory test evaluation, compliance assessment, and overall clinical assessment, both systemically and with each medication dispensing event. Required activities, including those noted previously, were developed to leverage the pharmacists’ expertise and achieve the greatest benefit for Unity members taking these medications. This process required the scripting of patient management encounters to include initial patient assessment and education of therapy goals, preferences for means of contact, patient and pharmacy expectations for telephone communication and follow-up, and initial assessment of barriers to adherence.

Before each patient encounter, pharmacy staff must review the patient’s medical record for disease-specific information and assess medication adherence by evaluating recent prescription fill activity. During this adherence assessment, patients who have gaps exceeding five days, adherence risk factors (increased cost, formulary changes), or other notable findings during a telephone or face-to-face interview are referred to specialty clinic providers for follow-up. A comprehensive consultation is performed with each patient, focusing on administration technique, adverse-event mitigation, and adherence assessment and improvement. Symptom assessment and regular depression screening using the Patient Health Questionnaire 2 are completed by pharmacists biannually and are included as part of the clinical documentation in the patient’s medical record.4

Patient outcomes and required metrics

Meaningful reporting of quality metrics was necessary to reinforce the value of specialty pharmacy ser-
services in the care of specialty patients. Based on literature reviews and best evidence, pharmacy and health plan representatives worked to identify meaningful measures and set targets for future measurements to reinforce quality and value.

As adherence to specialty medications is strongly correlated with patient outcomes, aggressive goals measured by the medication possession ratio (MPR) were established for each specialty disease. The specialty pharmacy must report an annual aggregate MPR for all plan members within each specialty disease as well as individual patient MPRs; individuals who do not meet payer goal adherence values are targeted for pharmacist-based adherence interventions.

Persistence, defined as maintaining therapy with an appropriate specialty medication over the measurement period, is reported annually for patients receiving specialty medications. In addition, therapies with finite treatment periods (such as therapies for hepatitis C virus infection) are reported as the percentage of patients completing the intended course of therapy, and reasons for noncompletion should be identified. In the case of hepatitis C therapy, sustained virological response rates are reported annually with other combined reporting requirements.

Other metrics include reporting the number of plan members using specialty pharmaceuticals by disease and providing reports of pharmacists’ interventions. These may include dose modifications, the management of drug–drug interactions or adverse drug reactions, and interventions to improve patient adherence.

Longitudinal benefits

The development of a collaborative, outcomes-based specialty contract offers significant benefits to a health-system–based specialty pharmacy. With the approval of new specialty medications and treatments in new therapeutic areas, the contract affords the opportunity to quickly expand the scope of third-party payer contracted specialty services. The scope of contracted services via this payer–pharmacy contractual relationship also drives the requirement for pharmacist competence in patient management for core diseases and can streamline future contractual negotiations with pharmaceutical manufacturers and third-party payers. Many external contracts with third-party payers and pharmaceutical manufacturers require the demonstration of competence through established patient volumes, which may be difficult to attain without a preferred contractual relationship with a third-party payer.

The contractual relationship also confers benefits to the third-party payer. Through the collective focus on total cost of care and transitioning patients away from hospital-based infusion centers in favor of home infusion or home administration, payers provide more value to their customers through better management of specialty drug costs and deliver better patient outcomes from their specialty drug spend. The visibility of documented pharmacy interventions and positive patient outcomes data also serve as a differentiator when negotiating contracts with additional clients. The collaborative development of practice standards, service requirements, and patient management protocols offers the rapid elevation of specialty pharmacy services, which provides significant differentiation within the highly competitive specialty pharmacy and third-party payer marketplaces.

Conclusion

Establishing collaborative and outcomes-based specialty pharmacy contracts with regional third-party payers can create a framework to maximize patient outcomes from specialty drugs. Limitations that must be overcome before implementation of such programs include defining the required patient outcomes or metrics (this may be challenging due to the paucity of comparable metrics within the clinical literature), developing documentation tools that do not currently exist within many standard EMR systems, redefining workflows within the specialty pharmacy to optimize patient contact time and efficiency, and creating patient engagement with pharmacy services. It also requires practice change management, as pharmacists move from product dispensing roles to focus on patient care practices and longitudinal patient management.

Disclosures

The authors have declared no potential conflicts of interest.

References

Appendix—Unity Specialty Pharmacy Network’s participation requirements

1. Pharmacies will participate in the Wisconsin Pharmacy Quality Collaborative (WPQC) and meet all WPQC best-practice requirements throughout the course of dispensing activities.

2. Pharmacies may dispense specialty medications directly to Unity plan members or by mail order. The pharmacy will provide patients with a toll-free number to facilitate this process.

3. Automatic shipment of medications is prohibited by Unity Specialty Pharmacy Network pharmacies.

4. Participating pharmacies must provide plan members with the necessary supplies needed to administer and dispose of specialty drugs at no additional cost.

5. Specialty pharmacies must have dedicated customer service representatives specific to specialty medications available to plan members during business hours.

6. Plan members must have access to a pharmacist during business hours.

7. Specialty pharmacies must fulfill medication fill requests within 48 hours and provide no-cost overnight shipping on weekdays.

8. Specialty medications will be shipped in a way necessary to preserve the integrity of the drug (e.g., appropriate temperature control), and the pharmacy will have procedures to ensure that these requirements are met and maintained.

9. Specialty pharmacies agree to meet all requirements of the established medication outcomes management program for each specialty drug.

10. Pharmacists must review the patient’s electronic medical record for pertinent laboratory values, interim clinical history, and other pertinent information before dispensing the medication.

11. Pharmacists must receive annual training in specialty disease states, including an annual hands-on device training session for all Unity-covered specialty injectables.

12. Pharmacists must achieve certification in an appropriate area of practice.

13. Specialty pharmacies must be accredited by the Utilization Review Accreditation Commission.