Las Vegas—Defining fair market value (FMV) for specialty pharmacy services, managing the rising costs of specialty medications and dealing with the fragmented care that can occur as a result of limited drug distribution networks were some of the topics addressed during a wide-ranging panel discussion at the 13th Annual MHA Business Summit. Although the issues may not be new to all stakeholders, they nevertheless can be powerful determinants of success in this increasingly competitive trade channel, the panelists agreed.

Burt Zweigenhaft, the president of the National Association of Specialty Pharmacy (NASP), who moderated the panel, said FMV is one of the more scrutinized and debated topics in this space. Key players, he noted, are still struggling to define FMV and determine its importance in placing a value—and price—on the many services that specialty pharmacies provide.

“We build all of this infrastructure to support high-touch patient care,” Mr. Zweigenhaft said. “But nothing is free; there are significant costs associated with these programs.” So the questions he posed to the panel were this: How does one establish FMV for specialty pharmacy services? And having done so, can manufacturers and specialty pharmacies work those estimates into contracting and other strategic partnerships?

**Feds Driving Value**

Panel member Julie DeLong, CFA, CVA, a managing director in the valuation practice at Navigant Consulting Inc., a Chicago-based firm that works with companies to establish FMV for specialty pharmacy services, agreed that FMV may be one of the hottest topics in specialty pharmacy. That’s partly due, Ms. DeLong noted, to increased government scrutiny of arrangements between pharmaceutical manufacturers and providers. “This has put the spotlight on specialty pharmacy services [furnished] to pharmaceutical manufacturers and has increased the need for FMV analysis to support payments for these services,” she said.

Ms. DeLong echoed Mr. Zweigenhaft’s point that there are currently no workable, standardized definitions for the type of services that would be considered “bona fide” in fee-for-service arrangements. (Although the term “bona fide” is defined in a federal regulation on fees paid by manufacturers known as 42 CFR 447.502, it does not provide any guidance on whether a specific service would be considered bona fide.)
“Manufacturers have been in fee-for-service arrangements for wholesale drug distribution for a long time and have experience with what services should be considered bona fide,” Ms. DeLong said. “For many of them, however, specialty product distribution is a new concept; it’s foreign territory.” Thus, defining bona fide services in the latter setting remains a challenge, she noted.

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—Burt Zweigenhaft

Part of that determination “will hinge on deciding what services are considered core versus enhanced,” Ms. DeLong explained. “Those decisions are certainly very integral to government pricing.”

The problem is that not all specialty pharmacies provide the same services, whether they be clinical counseling, Risk Evaluation and Mitigation Strategy compliance, cold chain management, data track and reporting, adherence monitoring or any other component of the specialty pharmacy business model. Indeed, as many of the panelists noted, if you’ve seen one specialty pharmacy, you’ve seen one specialty pharmacy.

Acknowledging those challenges, Mr. Zweigenhaft asked the panel to comment on “how we can get to a universal definition of fair market value” for specialty pharmacy, and in doing so, establish when the work component “rises above the core services we all provide in dispensing and purchasing.”

In Ms. DeLong’s view, “we’re not there yet; there still isn’t agreement” among manufacturers and specialty pharmacy providers. That’s not to say, however, that future efforts won’t help to bring consistency, she stressed. “I think it will be a while, but certainly the industry could take a proactive view on this, and perhaps work toward a common understanding on which services are considered core or enhanced.”

Tom Nusbickel, the head of U.S. Market Access, Biologics, at Hospira, now a Pfizer company, tackled FMV from a manufacturer’s perspective. There’s no doubt, the panelist noted, that “specialty pharmacy providers deliver meaningful services to patients.” However, “as manufacturers, we’re being asked to spell out very clearly why those services are necessary—why it’s not something that could be done by someone else, for example, potentially at a lower cost. So we have to apply a reasonable test and determine, with appropriate standards for evaluation, fair market value” in such settings, he said.

Mr. Nusbickel said the debate over FMV is not going away. “These areas are under a lot of scrutiny,” he stressed.

Mr. Zweigenhaft said the profession should encourage such scrutiny. “If we are willing to re-engineer the health care system for physicians so that reimbursement is not based on how much care is provided, but instead on the quality and value of that care, then we need to do that for specialty pharmacy as well. It’s time to get serious about this, and NASP is on it.”

To that end, NASP has convened a task force to define FMV, he noted. “We are looking for bright minds and folks who feel they can really help us solve this puzzle.” Those interested can contact Mr. Zweigenhaft at burt_zweigenhaft@me.com.

Performance-Based Contracting

Weaving his own experience into the discussion, Mr. Zweigenhaft noted that performance-based contracting is becoming an increasingly more common tool for setting payments for specialty pharmacy services. “We’re starting to see manufacturer agreements with payors stating, ‘Well, if you don’t
achieve the clinical or data reporting outcomes you promised, you’re not going to get full reimbursement. Or maybe we’ll ask for a refund.”

Mr. Zweigenhaft added a caveat, however: For performance-based contracting to work optimally, data aggregation and reporting need to be spot-on. “For some providers, that may be a challenge,” he said, “because we are not as transparent as an industry as we used to be.” New, smaller operators trying to break into specialty also may find data reporting to be a barrier to entry, he added.

Complex, High-Cost Care

One key area of performance for specialty pharmacy providers is to achieve high rates of medication adherence, Mr. Zweigenhaft noted—a point echoed by panelist member Dino Martino, RPh, the executive director and general manager of PerformSpecialty, an accredited provider based in Orlando, Fla. And that’s understandable, Mr. Martino said, given the high cost of specialty medications. He noted that one of the first spotlights on cost was shone on sofosbuvir (Sovaldi, Gilead), which was approved in 2013 for the treatment of chronic hepatitis C. The drug launched with the then-hefty price tag of about $84,000, but because it is potentially curative, sofosbuvir typically results in a one-time cost to the health system for a given patient, he noted. That’s in stark contrast to other, more recently approved specialty pharmacy drugs, such as those for hemophilia, cystic fibrosis and other chronic, complex diseases. For those disorders, treatment can cost hundreds of thousands of dollars per year—essentially for the lifetime of the patient.

Given such cost pressures, Mr. Martino noted, it’s not surprising that manufacturers want proof from providers that patients are actually taking their medications. But beyond that, they also want to know that providers can ensure that the efficacy for specialty drugs cited in clinical trials “is actually being replicated in real-world clinical settings,” he said.

In those trials, “you remove all of the variables we know can get in the way of achieving the best results,” he said. “That’s where we step in as providers; we help patients manage their complex diseases and treatments. That’s why specialty pharmacy as an industry still exists and will continue to exist—as long as we keep the patient foremost in our business models.”

Debating Limited Distribution

Audience members were invited to ask questions of the panel, and several focused on the burdens that can result when specialty drugs are placed in limited distribution networks. One long-term care (LTC) provider said “it is terrible” that operators in the LTC space often don’t have access to such networks. She cited fragmentation of care as one key downside. “These are extremely fragile patients we’re talking about,” she said, and it’s hard enough to manage their polypharmacy without having to add a different pharmacy provider into the care equation.

Given those concerns, she asked, “is it possible that we might see some special dispensation going forth, to allow LTCs greater access to some of these limited distribution drugs?”

Several panel members cited the need for LTC providers to be accredited as a baseline condition of participation for joining a limited distribution network. Panelist Heather Bonome, PharmD, the director of pharmacy at URAC, one of the nation’s top pharmacy accreditors, stressed, however, that if an LTC entity decides to pursue specialty pharmacy accreditation as means of network entry, “that’s not a long-term care-focused review process; we’ll be looking at your overall ability to deliver specialty pharmacy services.” LTCs thus need to have a broad understanding of how their capabilities will be assessed, she stressed.

Mr. Martino said he understands from first-hand experience the frustrations providers feel when they are closed out of specialty drug networks. “It’s difficult when we know that we’re supplying
the same—and sometimes even better—service than the bigger providers, and yet we aren’t granted access,” he said. In such scenarios, “you have to be ready to battle, to set yourselves apart, to be included.”

Mr. Martino acknowledged, however, that limited distribution networks are limited for a reason. “Every time a manufacturer gives a provider access to their specialty product—particularly drugs that are highly complex, that have a high degree of sensitivity around their use and that require considerable clinical oversight—that’s another provider they need to monitor for multiple levels of compliance.”

Get Involved
Mr. Zweigenhaft said he recognizes there are no easy answers to solving the complex practice issues tackled by the stakeholder panel. But one thing is very clear, he noted: with the specialty drug spend continuing to rise at a record-setting pace, and the pipeline for new specialty medications ever-widening, “we need to keep this debate going—and that’s a great opportunity for all stakeholders to get involved and shape the future direction of our industry.”

—David Bronstein