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White-Bagging vs. Buy-and-Bill: Practical Considerations for Physicians Administering Specialty Pharmaceuticals

Kathryn S. Burnett

Kathryn S. Burnett is a senior associate in the Tulsa, Oklahoma office of Conner & Winters LLP. Her practice focuses on health care compliance and provider reimbursement. Contact her via email at kburnett@cwlaw.com.

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Introduction

The field of specialty pharmaceuticals has seen tremendous growth in recent years as pharmaceutical companies have developed and brought to market an increasing number of drugs and biologics designed to treat complex, chronic, and acute conditions such as cancer, multiple sclerosis, and chronic immunological conditions.[1] These medications "are complex to manufacture, can be difficult to administer, may require special patient monitoring, and sometimes have . . . FDA-mandated strategies to control and monitor their use," as well as specific requirements for their safe distribution, storage, and handling.[2] In addition, while an increasing number of specialty pharmaceuticals may be self-administered or administered through home infusion,[3] a substantial number continue to require physician administration through injection or infusion in an office or hospital setting.[4] Despite these burdens, the use of specialty pharmaceuticals continues to increase. It is estimated that "[b]y 2018, 7 of the 10 top-selling drugs in the United States [will] be specialty pharmaceuticals, compared with 3 in 10 today."[5]

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1 In 2013, "[t]he top [three] specialty therapy classes [were] inflammatory conditions, multiple sclerosis, and cancer . . . [while other] areas of high use and growth [were] human immunodeficiency virus (HIV), growth deficiency, anticoagulants, hepatitis C, transplant, respiratory conditions, and pulmonary hypertension." Courtney J. Patterson, *Best Practices in Specialty Pharmacy Management*. 19 J. Managed Care Pharmacy 42 (2013), *available at* www.amcp.org/WorkArea/DownloadAsset.aspx?id=16078.

2 Ian Spatz & Nancy McGee, *Health Policy Brief: Specialty Pharmaceuticals*, Health Aff., Nov. 25, 2013 [hereinafter *Health Policy Brief: Specialty Pharmaceuticals*], *available at* http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_103.pdf.

3 Magellan Pharmacy Solutions /ICORE Healthcare, Medical Pharmacy & Oncology Trend Report 26 (3rd ed. 2012) [hereinafter Medical Pharmacy & Oncology Trend Report], *available at* http://magellanrxinsights.com/wp-content/uploads/dlm_uploads/2014/10/10370M_TrendReport_Q4-12_final.pdf.

4 Jack McCain, *Connecting Patients with Specialty Products: Part 2: The Future of Specialty Drug Distribution*, Biotechnology Healthcare 13, 15 (2012) [hereinafter *Connecting Patients with Specialty Products: Part 2*], *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3474456/pdf/bh0903013.pdf. *See also* Medical Pharmacy & Oncology Trend Report, at 26.

5 *Connecting Patients with Specialty Products: Part 2*, at 13.

These medications provide hope to patients and new treatment options to physicians, but "because many specialty pharmaceuticals are one-of-a-kind products developed for small patient populations,"[6] they also come at significant cost. While "the overall drug cost trend is essentially flat for nonspecialty therapeutics, specialty drug costs are escalating at an unprecedented rate."[7] The specialty pharmaceutical market is valued at more than $77 billion, with annual market share growth estimated at nearly 9%.[8] The cost of some specialty pharmaceuticals for an individual patient "can be in the thousands of dollars a month and can [even] exceed $100,000.00 a year"[9] as manufacturers set higher prices to recover a drug's research and development costs.[10] Acquiring and administering specialty pharmaceuticals has become an increasingly complex and cost prohibitive undertaking for physicians who administer these medications in-office.[11] As public and private payers struggle to balance "the enormous promise of biologic [specialty pharmaceutical] products with the costs of insuring plan members, in addition to fulfilling supply conditions that ensure proper storage, delivery and ongoing patient compliance with relatively complex

6 Jack McCain, *Connecting Patients with Specialty Products: Part 1: Distribution Models for Biologics and Other Specialty Pharmaceutical Products*, Biotechnology Healthcare 8, 8 (2012) [hereinafter *Connecting Patients with Specialty Products: Part 1*], *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3411231/pdf/bh0902008.pdf.

7 Michael S. Jacobs & Kyle A. Johnson, *Curbing the Costly Trend: Exploring the Need for a Progressive Approach to the Management of Specialty Pharmaceuticals under the Medical Benefit*, 5 Am. Health & Drug Benefits (2012) [hereinafter *Curbing the Costly Trend*], *available at* www.ahdbonline.com/issues/2012/july-august-2012-vol-5-no-5/1046-feature-1046.

8 Pharm. Commerce, *Specialty Pharmaceuticals: Facts and Figures* (Dec. 27, 2012), *available at* www.pharmaceuticalcommerce.com/index.php?pg=special_report&articleid=26720.

9 *See Health Policy Brief: Specialty Pharmaceuticals.*

10 *See* Sanjay K. Rao, *Pricing Biologics: Issues, Strategic Priorities and a Conceptual Model*, 17 J. Commercial Biotechnology 7, 8 (2011) [hereinafter *Pricing Biologics*], *available at* www.palgrave-journals.com/jcb/journal/v17/n1/pdf/jcb201030a.pdf.

11 *Health Policy Brief: Specialty Pharmaceuticals*; *see also* Lujing Wang et al., *Turning Tides: Trends in Oncology Market Access* (2012) [hereinafter *Turning Tides*], *available at* www.campbellalliance.com/articles/Campbell%20Alliance%20-%20Turning%20Tides%20-%20August%202012.pdf.

modes of drug intake,"[12] two primary methods of acquiring provider-administered specialty pharmaceuticals have emerged: "buy-and-bill" and "white-bagging." In buy-and-bill, physicians purchase pharmaceuticals and bill the payers for the cost of the drugs when the drugs are administered.[13] In white-bagging, the physician receives the patient's prescribed pharmaceuticals from a specialty pharmacy and bills the payer only for the drug's administration.[14] The purpose of this Practice Resource is to help physicians and their counsel choose how to best provide specialty pharmaceuticals in-office, as well as provide guidance on trends and issues for other buyers/providers of these medications. It provides an overview of the buy-and-bill and white-bagging processes, and identifies and explains the factors that physicians providing in-office administration of specialty pharmaceuticals should consider when deciding whether to utilize either or both methods to acquire specialty pharmaceuticals for their patients.

Acquiring Specialty Pharmaceuticals through the Traditional Buy-and-Bill Process

Traditionally, physicians administering specialty pharmaceuticals in their offices have purchased medications directly from manufacturers or through wholesale distributors and billed the patient's insurers for the cost of the medications incident to their administration.[15] Buy-

12 *Pricing Biologics*, at 8; *see also Health Policy Brief: Specialty Pharmaceuticals*; *see also Turning Tides*.

13 Magellan Rx Mgmt., Medical Pharmacy Trend Report 14 (2014) [hereinafter Medical Pharmacy Trend Report], *available at* www.magellanofnewyork.com/media/779171/layout9_10370m_trend_report_2013.pdf.

14 Acad. of Managed Care Pharmacy, AMCP Guide to Pharmaceutical Payment Methods, 2013 Update, at 50 (2013) [hereinafter AMCP Guide to Pharmaceutical Payment Methods 2013]; *see also* Abigail Jenkins, *Part 1—White-Bagging: White Knight or Villain?*, 2 Wharton Health Care Q. (2013) [hereinafter *White Knight or Villain*], *available at* www.whartonhealthcare.org/article.html?aid=1572.

15 Stephen Lash, *Learning to Love Your Specialty Pharmacy: Perspectives on a New Business Relationship*, 4 Biotechnology Healthcare 45 (2007) [hereinafter *Learning to Love Your Specialty Pharmacy*], *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC2651717/; *see also White Knight or Villain*.

and-bill is the required acquisition method for Medicare fee-for-service providers,[16] and it also remains popular with many private payers, particularly with regard to oncolytics, or cancer treatment therapies.[17] In the last ten years, however, Medicare and the majority of private payers have significantly shifted how they calculate the rates at which physicians are reimbursed for buy-and-bill acquired specialty pharmaceuticals, resulting in a corresponding increase in the financial burden experienced by many buy-and-bill physicians providing in-office administration of these drugs.[18]

Beginning in the 1960s, reimbursement rates paid to providers for in-office administered pharmaceuticals were based on the drug's Average Wholesale Price (AWP),[19] "a list price set by manufacturers"[20] that "almost every U.S. government and private payer used AWP . . .

16 Ctrs. for Medicare & Medicaid Servs., Medicare General Information, Eligibility, and Entitlement: Chapter 3–Deductibles, Coinsurance Amounts, and Payment Limitations (Pub. 100-01, Rev. 89, 11-21-14) [hereinafter Chapter 3], *available at* www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c03.pdf; Ctrs. for Medicare & Medicaid Servs., Medicare Claims Processing Manual: Chapter 17–Drugs and Biologicals (Pub. 100-04, Rev. 3055, 08-29-14) [hereinafter Chapter 17], *available at* www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.

17 A 2013 survey of 48 private payers representing 166.3 million beneficiaries revealed that approximately 40% of all injectable or infused drugs administered in physicians' offices were acquired and reimbursed via buy-and bill; when limited to in-office administered oncolytics, this number increased to 75%. Medical Pharmacy Trend Report.

18 *See, i.e.,* Medicare Payment Advisory Committee, Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs 5 (2007) [hereinafter Impact of Changes in Medicare Payments for Part B Drugs], *available at* www.medpac.gov/documents/reports/jan07_partb_mandated_report.pdf?sfvrsn=0 (reporting that "[m]ost physicians have told us that they can still buy most drugs at the Medicare payment level [of ASP + 6%], but all report that margins are slim and there are some drugs they cannot purchase at the [Medicare] payment rate. Physicians, particularly oncologists . . ., report spending considerable time and staff resources seeking the best deals for drugs."). *See also* AMCP Guide to Pharmaceutical Payment Methods 2013, at 56 (noting that, though "ASP has been shown to be an effective method to significantly reduce drug payments for Medicare," . . . "[w]ith ASP, it is the end provider of services . . . whose gross margin is most affected.").

19 Acad. of Managed Care Pharmacy, AMCP Guide to Pharmaceutical Payment Methods, Version 1.0, at 10 (2007) [hereinafter AMCP Guide to Pharmaceutical Payment Methods 2007].

20 Cindy Parks Thomas, Health Industry Forum, Key Medicare Issues for Coverage and Reimbursement of Specialty Pharmaceuticals 6 (2008) [hereinafter Key Medicare Issues for Coverage and Reimbursement of Specialty Pharmaceuticals], *available at* http://healthforum.brandeis.edu/meetings/materials/2008-16-July/Thomas-Background-Paper.pdf.

as its primary benchmark for [setting] reimbursement" rates through 2004.[21] Because manufacturers set the AWP for specialty drugs, they could offer providers discounts off the AWP without sacrificing their own profit margins. Discounts of 5-10% in the 1980s and up to 15% in the 1990s were common.[22] Providers purchasing specialty pharmaceuticals at these discounted rates were then reimbursed by Medicare and other insurers at an undiscounted or minimally discounted[23] AWP rate, "resulting in considerable provider profits"[24] on drugs for which a manufacturer's AWP represented artificially inflated prices, rather than truly "reliable indicators of [a drug's] average wholesale price[]."[25] These profits covered overhead items associated with in-office administration, including additional nursing support; facilities designed for the safe handling, mixing, and compounding of specialty pharmaceuticals; and incidental supplies associated with injection and infusion services.[26] In 2003, however—against a backdrop of increasing Medicare costs[27] and concerns that the profit margins physicians were

21 AMCP Guide to Pharmaceutical Payment Methods 2007, at 10.
22 *Id.*
23 *See* James M. Spears & Terry S. Coleman, Wash. Legal Found., *States' Use of Lawsuits to Regulate Drug Pricing Threatens Patients' Health*, 18 Legal Backgrounder 1, 2 (2003) [hereinafter *States' Use of Lawsuits to Regulate Drug Pricing Threatens Patients' Health*], *available at* www.wlf.org/upload/062703LBSpears.pdf (Internal citations omitted).
24 Key Medicare Issues for Coverage and Reimbursement of Specialty Pharmaceuticals, at 6.
25 *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers: Joint Hearing Before the Subcomm. on Health & the Subcomm. on Oversight & Investigations of the Committee on Energy and Commerce of the House of Representatives,* 107th Cong., 1st Sess. 3–4 (2001) [hereinafter *Medicare Drug Reimbursements*] (statement of J. C. Greenwood), *available at* www.gpo.gov/fdsys/pkg/CHRG-107hhrg75756/html/CHRG-107hhrg75756.htm (noting that, "[m]ost drug companies establish AWPs that are, in fact, fairly reliable indicators of average wholesale prices, but in those instances where they do not, the difference between what providers actually pay and what Medicare reimburses results in . . . an unwarranted profit pocketed by the health care provider each time he or she utilizes that particular drug.").
26 *White Knight or Villain*.
27 *See* Patrick Mullen, *The Arrival of Average Sales Price*, Biotechnology Healthcare 48, 48 (2007) [hereinafter *The Arrival of Average Sales Price*], *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3541838/pdf/bh0403048.pdf (noting that Medicare spending on drug therapies covered by Medicare Part B increased "from $6.5 billion in 2001 to $10.9 billion in 2004," and that "[p]art of that increase was a result of the gap between estimated physicians' acquisition cost of drugs and the higher amount that Medicare reimbursed them.").

experiencing on particular drugs could lead providers to prescribe specialty pharmaceuticals for profit rather than medical appropriateness[28]—lawmakers revised Medicare's drug reimbursement benchmark from AWP to Average Sales Price (ASP) as part of the Medicare Modernization Act.[29] AWP is set by the manufacturer, but the ASP is a volume-weighted average price based on the manufacturer's quarterly sales reports for specialty pharmaceuticals.[30] By law, manufacturers must take into account nearly all drug discounts when calculating quarterly ASPs, including rebates, chargebacks, and discounts given for such things as volume purchasing and cash payments,[31] resulting in a drug price that "is substantially lower than [the] AWP" price.[32] For buy-and-bill physicians, this transition in reimbursement rate calculation meant, when billing for drugs administered to Medicare patients, reimbursement at 106% of ASP[33] rather than 95% of AWP.[34]

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28 *Medicare Drug Reimbursements*.

29 42 C.F.R. § 414.904. Though it became law in 2003, the change to ASP-based reimbursement was not implemented until 2005. AMCP Guide to Pharmaceutical Payment Methods 2013.

30 42 C.F.R. § 414.804.

31 *Id.*; *see also The Arrival of Average Sales Price*, at 49.

32 Dept. of Health & Human Svcs., Office of the Inspector Gen., Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price 1, 8 (2005), *available at* https://oig.hhs.gov/oei/reports/oei-03-05-00200.pdf (noting that, at the median, ASP on 2,077 different national drug codes was 49% lower than AWP).

33 42 C.F.R. § 414.904. The author notes that, though the regulatory language still reflects a Medicare reimbursement rate of ASP+6%, the federal sequestration budget cuts of 2013 effectively reduced reimbursement rates for both the acquisition and administration of physician-administered specialty pharmaceuticals. Currently, the effective reimbursement rate for physician-administered specialty pharmaceuticals is ASP+4.3%. *See* Christina Frangou, *Scrambling to Deal with Sequestration: Community Practices Brace for 28% Cut to Office Drug Payments,* 8 Clinical Oncology News (2013) [hereinafter *Scrambling to Deal with Sequestration*], *available at* www.clinicaloncology.com/PrintArticle.aspx?A_Id=23401&D_Id=155&D=Current+Practice. Legislation was introduced in both the House and Senate in 2013 to amend the formula for calculating the ASP for drugs and biologicals under Medicare by excluding manufacturers' customary prompt pay discounts for wholesalers when calculating ASP. The measure failed to make it out of committee. *See* H.R. 800, 113th Cong. (2013–2014), *available at* www.congress.gov/bill/113th-congress/house-bill/800 and S. 806, 113th Cong. (2013–2014), *available at* www.congress.gov/bill/113th-congress/senate-bill/806. Essentially identical legislation has since been reintroduced in the House and is currently in committee. *See* H.R. 696, 114th Cong., *available at* www.congress.gov/bill/114th-congress/house-bill/696.

34 *See States' Use of Lawsuits to Regulate Drug Pricing Threatens Patients' Health*, at 2.

The intention of the ASP+6% reimbursement rate is that the dollar value of a specialty pharmaceutical's ASP compensates a physician for purchasing the drug, while the additional 6% offsets additional overhead costs associated with the drug's acquisition, storage, handling, administration, and disposal—costs previously offset by the profit margins afforded by AWP-based reimbursement.[35] For many providers, however, there is a disconnect between the ASP and the actual price at which they are able to acquire specialty pharmaceuticals, because manufacturers' discounts included when calculating ASPs are often available only to large volume purchasers, such as specialty pharmacies and health care facilities, and rarely available to individual providers or small physician groups.[36] Providers with a high volume of Medicare patients may not break even on the cost of purchasing such specialty pharmaceuticals and may also find that overhead costs associated with acquiring, storing, and administering certain drugs cannot be covered by the 6% over ASP.[37] For them, "there is either no payment for the substantial services provided to store and prepare the drug for administration, or worse that the practice is paying to provide those services and also paying for a portion of the patient's needed therapy instead of Medicare."[38] For cancer drugs in particular, it is estimated that "for every

35 *See* Ted Okon et al., *Problems Facing Cancer Care with Medicare's Definition of Average Selling Price*, 1 Community Oncology 59, 59–60, 63 (2004) [hereinafter *Problems Facing Cancer Care with Medicare's Definition of Average Selling Price*], *available at* www.oncologypractice.com/co/journal/articles/0101059a.pdf.

36 *See* Impact of Changes in Medicare Payments for Part B Drugs; *see also Problems Facing Cancer Care with Medicare's Definition of Average Selling Price*, at 60; AMCP Guide to Pharmaceutical Payment Methods 2013.

37 *See The Arrival of Average Sales Price*, at 51; *see also Examining Reforms to Improve the Medicare Part B Drug Program for Seniors: Hearing Before the H. Energy & Commerce Health Subcomm.*, 113th Cong. (2013) [hereinafter *Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*] (submitted testimony of Dr. Barry Brooks, Chairman of Contracting Subcomm., U.S. Oncology Network), *available at* http://docs.house.gov/meetings/IF/IF14/20130628/101055/HHRG-113-IF14-Wstate-BrooksB-20130628.pdf.

38 *Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*, at 8; *see also* Rhett Johnson & Edward N. Freeman, *Addressing Costs and Continuity of Care through Innovative Solutions for Infused Therapies: A Collaborative Experience with Infliximab*, 4 Am. Health & Drug Benefits. 39, 40 (2011) [hereinafter *Addressing Costs and Continuity of Care through Innovative Solutions for Infused Therapies*], *available at* www.ahdbonline.com/issues/2011/january-february-2011-vol-4-no-1/611-feature-611.

$100 that a US-based community cancer clinic spends on purchasing cancer drugs, an additional $12 is spent on costs associated with billing and reimbursement, storage and inventory, pharmacy, documentation and overhead"[39] such that the break-even point for a buy-and-bill provider in this type of practice environment would be ASP+12%.

Compounding this problem is that many private payers began shifting to ASP-based models following Medicare's implementation of ASP-based reimbursement. By 2013, approximately 80% of individuals covered by private payers had coverage plans "that reimburse providers for medical benefit injectables [i.e., in-office administered specialty pharmaceuticals] based upon a percentage higher than" ASP.[40] In 2013, private payers using ASP-based reimbursement rates paid physicians 8% over ASP on average.[41] For some physicians, this may be sufficient to offset any Medicare-related losses; however, for others, such as those with higher overhead costs,[42] private payer reimbursement rates may still not be enough to cover costs of providing in-office administration of specialty pharmaceuticals. Nevertheless, an increasing number of private payers are relying on the buy-and-bill method. Among private payers in 2012, approximately 60% of physician-administered, infused chemotherapy drugs and approximately 36% of physician-administered, infused non-chemotherapy drugs were acquired and reimbursed using a buy-and-bill process.[43] By 2013, among private payers, approximately 75% of physician-administered, infused chemotherapy drugs and approximately 71% of physician-administered, infused non-chemotherapy drugs were acquired and reimbursed through a buy-and-bill process.[44]

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39 *Pricing Biologics*, at 10.
40 *See* Medical Pharmacy Trend Report, at 14; *see also Curbing the Costly Trend*.
41 *See* Medical Pharmacy Trend Report, at 15 (citing its survey of 40 payers covering 152 million lives in which the lowest reimbursement rate was 4% over ASP, the highest 30% over ASP, and the weighted mean 8% over ASP).
42 *Pricing Biologics*, at 10.
43 Medical Pharmacy & Oncology Trend Report, at 27.
44 Medical Pharmacy Trend Report, at 29.

The continued appeal of buy-and-bill acquisition, despite the potential impact to the bottom line, is that it gives providers more control over their patients' medications and administration and is more likely to ensure continuity of care. Buy-and-bill acquisition also allows providers to maintain a large inventory of specialty pharmaceuticals on-site that are available when needed, and "to tailor the exact dose and combination of drugs to [individual] patients" when they arrive for their appointments.[45]

For payers, the buy-and-bill process places the burdens of acquiring specialty pharmaceuticals (e.g., funding drug purchases, contracting with pharmacies, and complying with federal tracking and reporting requirements) on the physicians prescribing and administering them; reduces the payer's administrative burdens; and provides them with greater financial and drug utilization efficiencies. Payers pay on average 17% less and experience 20% less drug waste for drugs acquired through the buy-and-bill process as compared to drugs obtained from specialty pharmacies via the white-bagging process.[46]

White-Bagging as an Alternative Acquisition Model

The buy-and-bill method of calculating reimbursement rates was based on the premise that physicians were being paid too much for the specialty pharmaceuticals they prescribed and administered. White-bagging, on the other hand, grew from payers' concerns[47] that buy-and-bill created "inappropriate financial incentives"[48] that could

45 Suzanne Shelley, *Navigating the Tense, Complex Oncology Market*, Pharmaceutical Com. 4 (2012), *available at* http://pharmaceuticalcommerce.com/special_report?articleid=26548.

46 Medical Pharmacy & Oncology Trend Report, at 27.

47 As noted above, Medicare regulations limit coverage of specialty pharmaceuticals administered in a physician's office to the buy-and-bill model; therefore, the author's discussion of white-bagging and its implications presumes private payers and their beneficiaries. The author notes, however, that Medicaid programs are not similarly limited by federal regulations, and that some states' programs may utilize the white-bagging model.

48 Greg Bell, *Managing Office-Administered Drugs: An Economist's Perspective*, 10 J. Managed Care Med. 34, 35 (2007), *available at* www.namcp.org/Journals/JMCM/JMCM_V10N2_todb.pdf.

result in physicians' increased utilization of specialty pharmaceuticals for off-label purposes, as well as increase their prescription of more expensive specialty pharmaceuticals before determining whether other less expensive treatments might be effective.[49] The white-bagging model of acquisition is intended to "reduce payer costs associated with specialty drugs by ensuring proper utilization by physicians"[50] while improving patient outcomes through specialty pharmacies' "monitoring [of] patient compliance and adherence."[51]

In the white-bagging model, the physician submits a patient-specific prescription to a specialty pharmacy that is contracted with the patient's insurer, rather than purchasing the medication directly and billing the payer for its cost when the medication is administered.[52] The specialty pharmacy, typically staffed with specialist pharmacists and nurses who purchase, store, and deliver medication, will review and obtain the insurer's approval for the prescription, bill the insurer, and send the patient's filled prescription to the physician for administration.[53] Depending on the terms of its contract with a particular payer, the specialty pharmacy may offer such services as monitoring patient compliance, providing 24-hour telephone support and diagno-

49 *See* James C. Robinson, *Insurers' Strategies for Managing the Use and Cost of Biopharmaceuticals*, 25 Health Aff. 1205, 1211 (2006), *available at* http://content.healthaffairs.org/content/25/5/1205.full.html; Michael T. Einodshofer & Lars N. Duren, *Cost Management Through Care Management, Part 2: The Importance of Managing Specialty Drug Utilization in the Medical Benefit*, 5 Am. Health & Drug Benefits (2012), *available at* www.ahdbonline.com/issues/2012/september-october-2012-vol-5-no-6/1178-article-1178; *see also* Pamela Leigh Sauerwald, *Changing the Channel: Developments in US Specialty Pharmaceutical Distribution*, Pharmaceutical Com. (2009), *available at* www.pharmaceuticalcommerce.com/business_finance?articleid=1718&keyword=IMS%20Health-specialty%20pharmaceuticals-pharmacy-SPP-Sauerwald.

50 *White Knight or Villain*.

51 *Turning Tides*, *at* 4.

52 *See Curbing the Costly Trend*; *see also White Knight or Villain*.

53 *Navigating the Tense, Complex Oncology Market*; *see also White Knight or Villain*; *Pricing Biologics*.

sis-specific education for patients, and compiling drug utilization and patient outcome information.[54]

When a physician acquires specialty drugs through white-bagging, the cost of the drug itself is billed to the patient's payer by the specialty pharmacy, rather than the physician. The physician's claim to the payer is limited to her professional fee for administering the drug.[55] Unlike the ASP+ reimbursement rate available in the buy-and-bill context, the physician adopting the white-bagging method does not receive additional reimbursement to offset overhead costs,[56] such as costs associated with safely handling and storing multiple patient-specific prescriptions; hiring specialized personnel to administer the drugs and monitor patients during their treatments; safely disposing of unused specialty pharmaceuticals in compliance with applicable environmental laws; and coordinating prescription authorizations, orders, and shipment with multiple insurers, specialty pharmacies, and patients.[57] This may create a greater incentive for physicians to refer their white-bagging patients to hospital outpatient departments

54 *Learning to Love Your Specialty Pharmacy*, at 46.

55 *See* AMCP Guide to Pharmaceutical Payment Methods 2013, at 50; *see also* E.R. Anderson et al., *Challenging New Delivery Models for Injectable Drugs*, 8 Oncology Issues 8 (2010) [hereinafter *Challenging New Delivery Models for Injectable Drugs*], *available at* www.yumpu.com/en/document/view/24306511/challenging-new-delivery-models-for-injectable-drugs; *see* Kate O'Rourke, *'White Bagging' of Specialty Drugs Draws Some Ire: A hassle for health systems?*, 40 Pharmacy Practice News 1, 2 (2013), *available at* www.pharmacypracticenews.com/ViewArticle.aspx?d=Operations%2B%26%2BManagement&d_id=53&i=November+2013&i_id=1013&a_id=24488 (registration required).

56 Though physicians may be able to negotiate their rates of reimbursement for particular in-office drug administration codes and thereby potentially offset their additional overhead expenses, current CPT billing codes related to in-office drug administration do not include any billing codes specific to these types of administrative, overhead expenses. *See* Ctrs. for Medicare & Medicaid Servs., Chapter XI: Medicine: Evaluation and Management Services: CPT Codes 90000–99999 for National Correct Coding Initiative Policy Manual for Medicare Services 2–6, 28–29 (Rev. Jan. 1, 2015), *available at* www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html?redirect=/nationalcorrectcodinited/.

57 *See The State of Oncology Practice: A Discussion with Anupama Kurup Acheson, M.D*, OncLive, Oct. 2, 2013 [hereinafter *The State of Oncology Practice*], *available at* www.onclive.com/publications/oncology-business-news/2013/september-2013/The-State-of-Oncology-Practice; *see also Connecting Patients with Specialty Products: Part 2*, at 11.

for infusion and injection services,[58] potentially disrupting the continuity of patient care and increasing the overall treatment burdens for patients and their families.[59]

In addition, while white-bagging allows a physician to provide patients with costly drugs without funding the drugs' initial purchase, the process may disrupt or delay patient care while a specialty pharmacy obtains approval from the payer and fills and ships the patient's individualized prescription.[60] Treatment delays may re-occur if the dosage or timing of the patient's treatment must be altered.[61] Further, the physician's practice must retain and properly store the unused prescription and eventually provide those medications to the patient, if it can be appropriately administered at a later date, or discard the prescription entirely, wasting its contents. The physician is not permitted to provide the prescription to another patient because once the prescription has been filled for a specific patient, "the drugs cannot be returned or used for a different patient."[62]

Despite these potential drawbacks, white-bagging has supporters among both payers and providers. For payers, the white-bagging model can provide a greater degree of control over the types of specialty medications administered to beneficiaries and increase patient adherence.[63] Payers also generally have greater volume purchasing power than do individual or small group physician practices, thereby

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58 James C. Robinson, *Providers' Payment and Delivery System Reforms Hold Both Threats and Opportunities for the Drug and Device Industries*, 31 Health Aff. 2059, 2061–62 (2012); *see also Connecting Patients with Specialty Products: Part 1*, at 11; *Navigating the Tense, Complex Oncology Market*.

59 *Scrambling to Deal with Sequestration*.

60 *See, e.g.*, Rowena N. Schwartz et al., *NCCN Task Force Report: Specialty Pharmacy*, 8 J. Nat'l Comprehensive Cancer Network S-1 (2010), *available at* www.jnccn.org/content/8/Suppl_4/S-1.full.pdf+html [hereinafter *NCCN Task Force Report*].

61 *Curbing the Costly Trend*; *see also NCCN Task Force Report*, at S-8 (noting that white-bagging "does not allow for flexibility in dose or schedule changes, including dose modifications or discontinuation of therapy. . .").

62 *Navigating the Tense, Complex Oncology Market*, *at* 4.

63 *See Learning to Love Your Specialty Pharmacy*, at 46.

reducing payers' drug acquisition costs without limiting beneficiaries' access to specialty pharmaceuticals.[64]

For providers, white-bagging enables physicians to administer high-cost specialty pharmaceuticals to patients without incurring the financial and administrative burden of sourcing and purchasing the drugs directly from manufacturers and wholesalers.[65] White-bagging also allows physicians to avoid the financial risks associated with payer denials and nonpayment of patient cost-sharing amounts.[66]

While white-bagging means physicians do not receive additional reimbursement to help offset overhead expenses (in contrast to the percentage over ASP provided under buy-and-bill), practices may find that the relatively low-maintenance nature of white-bagged shelf-stable drugs, discussed in greater detail below, sufficiently limits any direct overhead costs, allowing the practices to provide these drugs to their patients without additional overhead offset. As with buy-and-bill, however, the white-bagging model of drug acquisition may not be

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64 *Navigating the Tense, Complex Oncology Market*; *see also* Abigail Jenkins, *Part 2: White-Bagging: White Knight or Villain?*, 2 Wharton Health Care Q. 34 (2013) [hereinafter *White Knight or Villain*], *available at* www.whartonhealthcare.org/images.html?file_id=B1NExqvONtM%3D.The white-bagging model can increase payers' costs, however, as the cost of acquiring specialty pharmaceuticals from a specialty pharmacy is "17% higher, on a weighted average basis," than acquiring the drugs from providers' buy-and-bill stock. In addition, purchased drugs may be wasted as described above. When the lost value of these drugs is included, the total cost to payers may be as much as 50% higher than the costs associated with buy-and-bill. *See Curbing the Costly Trend*; *see also White Knight or Villain*.

65 *White Knight or Villain*; *see also Connecting Patients with Specialty Products Part 1*.

66 *See Learning to Love Your Specialty Pharmacy*, at 47; *see also* Ed Silverman, *Business Savvy in the Age of Biologics*, 4 Biotechnology Healthcare 49, 50 (2007) [hereinafter *Business Savvy in the Age of Biologics*], *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3541853/pdf/bh0404049.pdf; *see Navigating the Tense, Complex Oncology Market*, *at* 4; *Connecting Patients with Specialty Products Part 1*, at 11; *see Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*, at 9 (noting, "it is quite rare for practices to be able to collect the entire Medicare allowable rate for Part B drugs . . . principally due to the 20 percent coinsurance responsibility facing beneficiaries, often of very expensive therapies. It has been the experience of practices in The US Oncology Network that approximately 25 percent of the beneficiary coinsurance (approximately 5 percent of the Medicare allowable) is uncollectible and ends up as bad debt.").

appropriate for every physician or group practice. Physicians should consider several factors when determining which drug acquisition model is best suited for their practices.

Factors to Consider when Selecting an Acquisition Model

Both the buy-and-bill and white-bagging models have benefits and drawbacks. Physicians who provide or want to provide in-office administration of specialty pharmaceuticals should consider the following factors—and assess them in relation to one another—to determine whether either or both models are suitable:

1. areas of medical specialty;
2. patterns of drug utilization;
3. patient population and payer mix;
4. space limitations and potential; and
5. available financial resources.

Evaluation of the buy-and-bill and white-bagging drug acquisition models is not intended to be an either-or proposition. Some physicians may determine that their practices can accommodate both models, while others may determine that, all factors considered, providing in-office administration of specialty drugs under either model is not a feasible option. Still others may determine that their practices are well suited for buy-and-bill or white-bagging, but not both. The following discussion distills these alternatives into examples that illustrate consideration of each factor.

Area of medical specialty

The area of medical specialty may be the most significant factor to be considered when evaluating drug acquisition models. Specialty pharmaceuticals appropriate for in-office administration are available for a variety of conditions, which means they may be prescribed by

physicians practicing in any number of medical specialties, including, but not limited to, internal medicine, rheumatology, neurology, immunology, gerontology, and oncology. However, the cost, nature of the drugs prescribed, and utilization requirements may differ significantly among physicians in different medical specialties. In addition, there may be significant differences in the patient populations and payer mixes seen across medical specialties, as well as in the annually adjusted Physician Fee Schedule reimbursement rates afforded to individual specialties.[67] As a result, a physician practice's size and specialization (including sub-specialization) will necessarily influence the practice's evaluation of the remaining factors.

For example, physicians in a large oncology practice may subspecialize in any number of areas of oncology such as pediatric, surgical, radiation, or gynecologic oncology, each with its own patterns of drug utilization, patient and payer mixes, and other unique characteristics that will impact the selection of the most appropriate drug acquisition model.[68] In contrast, a smaller oncology practice might be more likely to work within a single area of oncology, thereby limiting

67 For example, the 2015 Physician Fee Schedule resulted in an overall decrease in reimbursement in rheumatology, an overall increase in oncology and hematology, and no change in immunology. *See* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015, 79 Fed. Reg. 67548, 67988 (Table 93: CY 2015 PFS Final Rule with Comment Period Estimated Impact Table: Impacts of Work, Practice Expense, and Malpractice RVUs) (Nov. 13, 2014), *available at* www.gpo.gov/fdsys/pkg/FR-2014-11-13/pdf/2014-26183.pdf.

68 In the oncology example, Medicare reimbursement rates for intra-arterial chemotherapy administration decreased by only 2.89% between 2013 and 2014; however, reimbursement for intravenous chemotherapy administration decreased by 7.5%, and reimbursement for treatment related, non-chemotherapeutic infusions (such as those to support hydration or administer anti-nausea medications) decreased as much as 14%. *See* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, 78 Fed. Reg. 74230, 74683 (Dec. 10, 2013), *available at* www.gpo.gov/fdsys/pkg/FR-2013-12-10/pdf/2013-28696.pdf; *see also* Ctrs. for Medicare & Medicaid Servs., *Physician Fee Schedule Search*, www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx (last visited Apr. 13, 2015).

the scope of the practice's utilization patterns and other factors under consideration.

Drug utilization patterns

The volume and characteristics of drugs prescribed are important factors to consider when evaluating a practice's patterns of drug utilization. Examined below are the benefits and drawbacks of buy-and-bill and white-bagging acquisition of (i) "shelf-stable" drugs—drugs that do not require special storage or handling and pose little to no risk of expiring if administration is delayed—and (ii) chemotherapy or other hazardous pharmaceuticals that require special handling and/or individualized dosing.

Shelf-stable specialty pharmaceuticals

Under the buy-and-bill model, practices that frequently prescribe shelf-stable specialty pharmaceuticals may be able to access wholesalers' volume purchasing discounts because the drugs' shelf-stable nature makes it possible for the practice to purchase the drugs in larger volumes that will be used over time. Shelf-stable drugs' characteristics also limit additional associated overhead costs. For example, the osteoporosis and osteoarthritis drugs Boniva and Supartz are shelf-stable and packaged by their manufacturers in pre-filled syringes for physician administration,[69] limiting the practice's drug-related overhead expenses such that a public or private payer's ASP-based reimbursement would likely cover the practice's costs associated with acquisition and administration.

Other practices that utilize shelf-stable specialty pharmaceuticals may find that the white-bagging model works just as well or better than buy-and-bill, particularly for practices that are low-volume prescrib-

69 Boniva and Supartz are used to treat osteoporosis and osteoarthritis, respectively. *See* prescribing information at www.gene.com/download/pdf/boniva_injection_prescribing.pdf and http://supartzprofessional.com/images/DRG.pdf, respectively.

ers or have limited financial resources. The drugs' shelf-stable nature means there is little risk that a drug will ruin if administration must be delayed, and filled prescriptions will not require specialized storage between delivery and administration. White-bagging also protects physicians from up-front purchase investments and eliminates concerns about collecting patient cost-sharing amounts or payer reimbursement. Further, though white-bagging means physicians do not receive ASP-based reimbursement to offset overhead expenses, the relatively low-maintenance nature of shelf-stable drugs may limit direct overhead costs enough that practices can provide these drugs to patients without receiving any offset.

Drugs requiring special handling and/or individualized dosing

For physicians who frequently prescribe chemotherapy and other specialty pharmaceuticals that require special handling[70] and/or individualized dosing, the buy-and-bill model allows greater control over drug inventory and the timing of drug acquisition. The frequently high cost of such drugs may, however, prohibit practices from taking advantage of any available volume purchasing discounts. Even so, the percentage above ASP reimbursement afforded providers under the buy-and-bill model, while unlikely to cover all of a practice's drug-related overhead costs,[71] may help offset the potentially significant overhead costs directly related to the administration of these types of specialty drugs.

A notable benefit of using the buy-and-bill is that physicians can make last-minute adjustments to the mixture, dosage, and/or timing

70 By way of example, the chemotherapy drug Avastin must be protected from light, stored at temperatures between 36°-46°F and, once diluted for I.V. administration, must be used within 8 hours. *See* Prescribing Information for Avastin, *available at* www.gene.com/download/pdf/avastin_prescribing.pdf.

71 *Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*, at 4 (noting that, "[These] drugs must be stored at controlled temperatures, mixed to the proper dose and bagged for administration by trained pharmacists and admixture technicians within approved clean rooms that often cost tens of thousands of dollars in investments.").

of a medication's administration. For example, patients receiving chemotherapy may need to have the mixture or dosage adjusted or delayed due to variables related to the patient's lab results; response to the patient's last treatment; and/or indications of infection or other contraindications present on the day administration is scheduled.[72] Under the buy-and-bill model, physicians can assess these variables and have a drug mixture or dosage prepared from a ready inventory of medications just prior to administration. The physician can also delay treatment if necessary or utilize the drugs for a different patient, as appropriate.

On the other hand, physicians who acquire specialty pharmaceuticals that require special handling with the white-bagging method are spared the potentially significant out-of-pocket acquisition costs, as well as the risk of losses associated with payer denials and non-payment of patient co-pays, because payment for the drugs is coordinated directly between a specialty pharmacy and a patient's insurer. For some practices, this protection from uncertain drug-related losses[73] may be an acceptable trade for ASP-based overhead offsets. Other practices may determine, however, that without the payer offset afforded by buy-and-bill, overhead expenses associated with storing, handling, and administering specialty pharmaceuticals are simply too high to make white-bagging a feasible option. White-bagging non-shelf-stable drugs also deprives physicians of their ability to make the last-minute medication adjustments they can make under the buy-and-bill model.[74] When medications like chemotherapy are acquired through white-bagging, physicians must prescribe the mixture and dosage based on laboratory tests performed 2-3 days before the medication is administered. [75] If

72 *See, i.e., Curbing the Costly Trend.*
73 *See, i.e., Connecting Patients with Specialty Products Part 1*, at 11 (discussing the protection against loss that white-bagging offers providers, and noting the significant losses experienced by East Coast providers when Hurricane Irene knocked out power to drug-refrigeration units).
74 *See Navigating the Tense, Complex Oncology Market*, at 4.
75 *See Challenging New Delivery Models for Injectable Drugs.*

the patient's laboratory values change during that window of time, the physician may need to submit a new prescription order to the specialty pharmacy,[76] resulting in treatment delay for the patient. Further, as noted above, the prescription originally filled for the patient must be stored, and perhaps ultimately discarded, by the physician.[77]

Patient population and payer mix

A practice's patient population and payer mix will likely weigh significantly on whether buy-and-bill, white-bagging, or a hybrid of the two will best suit the practice's in-office administration of specialty pharmaceuticals. A practice's assessment of its patient population should consider patient demographics, financial characteristics, and the types of drugs generally utilized for treatments.[78] Similarly, when evaluating its payer mix, a practice should consider the specific payers with which it has contracts and determine which ones require buy-and-bill or white-bagging, as well as the cost-sharing requirements of each payer.

For example, the majority of patients in an adult oncology practice will likely be Medicare beneficiaries, as more than half of all cancer patients in the United States are 65 years or older.[79] Medicare requires that physician-administered specialty pharmaceuticals be acquired through buy-and-bill acquisition.[80] An adult oncology practice might therefore conclude that buy-and-bill is a suitable model. Such a con-

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76 *See Navigating the Tense, Complex Oncology Market*, at 4; *see also Challenging New Delivery Models for Injectable Drugs*, at 8.

77 *See Curbing the Costly Trend*; *see also Navigating the Tense, Complex Oncology Market*, *at* 4.

78 These suggested assessments need not contain detailed information about specific patients; rather, they are intended to be general aggregations of information that physicians can utilize to evaluate the suitability of buy-and-bill and white-bagging for their practices.

79 *See* Angela B. Mariotto et al., *Projections of the Cost of Cancer Care in the United States: 2010–2020*, 103 J. Nat'l Cancer Inst. 117, *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3107566/.

80 Chapter 3; Chapter 17.

clusion would, however, be based on incomplete information if the practice did not also consider the cost of the specialty pharmaceuticals typically prescribed for its Medicare patients and evaluate (based on physicians' experiences and patient communications) whether those patients can afford Medicare's 20% patient co-pay (whether through supplemental insurance or their own financial resources), as the practice will have to absorb the loss of any unpaid co-pay amounts.[81] If, after considering the additional information, the practice determines it can handle the financial loss on at least some drugs provided to some of its Medicare patients—and the practice wants to continue treating them in-office if possible—the practice will need to examine the remainder of its patient population and payer mix to determine whether those payments and reimbursements will offset Medicare-related losses. If so, the practice may conclude it is willing to accept the financial loss associated with treating some of its Medicare patients in order to continue treating the majority of its patients within the office setting. If, however, payment and reimbursement from the remaining patient population and payer mix is insufficient to cover Medicare losses, the practice will need to consider other options for providing specialty pharmaceuticals to its Medicare patients,[82] such as providing lower-cost specialty pharmaceuticals[83] within the office and sending patients whose drugs exceed a certain cost threshold to a hospital outpatient department for treatment. Alternatively, if most of its patients' payers required or permitted white-bagging, a practice might consider forgoing buy-and-bill altogether; limiting the practice's in-office administration services to patients receiving white-bagged specialty pharmaceuticals, and sending Medicare and other buy-and-bill patients to the hospital for treatment.

81 *See, i.e., Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*, at 9.
82 *See Navigating the Tense, Complex Oncology Market*, at 4.
83 The drug Cisplatin, for example, is available as a generic drug, and therefore costs less than chemotherapy drugs only available as brand-name products. For a woman with ovarian cancer who is 5 ½ feet tall and weighs 120 lbs., a 100mg dose of Cisplatin (given every 4 weeks) costs just $34.44.

Practice space limitations and potential

As a preliminary matter, a practice must determine whether its space will accommodate physicians' in-office administration of specialty pharmaceuticals.[84] A practice that provides in-office administration must be able to handle, store, and administer such medications safely.[85] A practice's drug utilization patterns and available financial resources will likely bear significantly on the suitability of a particular space and on a practice's ability to make any necessary renovations.[86] For practices utilizing shelf-stable pharmaceuticals, such costs may be fairly minimal; however, for practices utilizing drugs that are hazardous and have specialized storage requirements, these costs can be substantial.[87]

Shelf-stable specialty pharmaceuticals

Physicians whose in-office administration services are limited to shelf-stable specialty pharmaceuticals may find that their current prac-

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84 *See* John F. Foley & Anne M. Dunne, *Successful Management of a Neurology Infusion Practice*, 13 Int. J. MS Care 95, 97 (2011) [hereinafter *Successful Management of a Neurology Infusion Practice*], *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3882956/pdf/i1537-2073-13-2-95.pdf.

85 *See, i.e., Successful Management of a Neurology Infusion Practice*, at 99–100. Because each state may have its own statutes and regulations governing physicians' safe, in-office storage, handling, and administration of specialty pharmaceuticals, the discussion of these concepts here is limited to physicians' adherence to manufacturers' recommendations and applicable federal laws, regulations, and agency guidance.

86 *See, i.e., Business Savvy in the Age of Biologics*, at 50 (discussing the importance of economy of scale to a practice's successful provision of in-office administration services); *see also Examining Reforms to Improve the Medicare Part B Drug Program for Seniors,* at 3–4 (discussing the potential costs of modifying a practice space to accommodate the administration of chemotherapy and other hazardous drugs); *see Addressing Costs and Continuity of Care through Innovative Solutions for Infused Therapies*, at 40 (noting the potential investments in infrastructure that practices may have to have to make to accommodate in-office drug administration).

87 *See* Al Heller, *Weighing the Options for Optimal Chapter <797> Compliance*, 36 Pharmacy Prac. News (2009) [hereinafter *Weighing the Options for Optimal Chapter <797> Compliance*], *available at* www.pharmacypracticenews.com/PrintArticle.aspx?A_Id=14277&D_Id=52&D=Technology; *see also Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*, at 3–4; Firouzan Massoomi, *CSTDs as a Cost of Doing Business,* Pharmacy Purchasing & Products 10 (2012) [hereinafter *CSTDs as a Cost of Doing Business*], *available at* www.pppmag.com/article_print.php?articleid=1234.

tice spaces are well-suited for providing such services.[88] For example, an extra examination room would require little, if any, modifications to convert it into a dedicated room for administering specialty pharmaceutical injections and infusions. The practice should keep in mind, however, the importance of safely storing its specialty medications, the costs related to safe and adequate storage, and how its storage capability may be affected by the unique characteristics inherent in buy-and-bill and white-bagging acquisition methods. For example, a practice utilizing buy-and-bill may wish to purchase in large quantities to obtain a volume purchasing discount. Before doing so, however, the practice's physicians should determine whether they have the type and amount of space necessary to appropriately store and safeguard such a large inventory. If not, the practice could lose any financial benefit through damaged, lost, or stolen pharmaceuticals.[89]

In the case of white-bagging, each patient-specific order received from a specialty pharmacy must be safely stored until the drugs are administered to the appropriate patient or discarded.[90] Ideally, patients would appear for their appointments and receive their prescribed medications on schedule, keeping a practice's white-bagging storage needs fairly constant, increasing or decreasing only in response to changes in physicians' utilization patterns. In practice, however, providers often have accumulations of white-bagged drugs that must be stored, maintained, and potentially discarded at providers' expense.[91] Consequently, the practice should carefully assess its utilization patterns, frequency of missed appointments, and drug administration delays to determine how much space is needed to store current and "stale" patient-specific prescriptions.

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88 *See Successful Management of a Neurology Infusion Practice*, at 97.

89 Depending on the state in which it is located and the specific nature of the drugs at issue, a practice dealing with damaged, lost, or stolen drugs could also face the administrative and financial burdens of fines and agency reporting requirements.

90 *See Challenging New Delivery Models for Injectable Drugs*, at 8.

91 *See id.*, at 9.

If a practice chooses to utilize both buy-and-bill and white-bagging models, its logistical burdens related to shelf-stable drug storage and space limitation may increase, as the practice must ensure that it maintains its buy-and-bill drug stock separately from its white-bagged stock.[92] As discussed previously, a white-bagged prescription arrives at a provider's office having been paid for by the patient or his insurer. If the practice's buy-and-bill and white-bagging stocks are not sufficiently separated, it increases the risks that a buy-and-bill patient will be administered a white-bagged prescription (a form of insurance fraud[93]) or buy-and-bill stock will be used to treat a patient whose insurer has already paid for a white-bagged prescription.[94] If the practice does not have adequate space to separate its buy-and-bill stock from its white-bagged stock, the practice may need to limit its acquisition of drugs for in-office drug administration to only one of the acquisition models and/or determine if it has the financial resources to obtain additional storage space or construct an appropriate storage area within the confines of its existing practice space.

Drugs requiring special storage and handling

Safe and adequate storage of non-shelf-stable pharmaceuticals, such as chemotherapy and other drugs that require special handling

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92 *See* Fred J. Pane, *White Bagging: A New Challenge for Your Hospital*, 36 Pharmacy Prac. News 1, 2 (2009), *available at* http://pharmacypracticenews.com/ViewArticle.aspx?d=Operations%2B%26amp%3B%2BManagement&d_id=53&i=December%2B2009&i_id=587&a_id=14378 (discussing the importance of having separately designated areas for storage of white-bagged and buy-and-bill medications) (registration required).

93 *See Challenging New Delivery Models for Injectable Drugs*, at 9 (noting that, "[i]t is insurance fraud if a patient-specific medication is given to another patient [because] [t]hese drugs have already been billed to the insurance companies.").

94 The risk of this type of error is primarily financial, in that the practice cannot bill the patient's insurer for the cost of the stock drugs used to treat the patient, because the patient's insurer has already paid for the patient's drugs and provided them to the physician for administration. Consequently, the practice will be out the cost of its buy-and-bill stock and will have to maintain its storage of the patient's white-bagged prescription.

or customized dosing, are subject to significant regulations[95] and strict industry standards regarding handling, storage, preparation, administration, and disposal,[96] regardless of the way in which they are acquired. Compliance may require physician practices to make significant and costly[97] investments in equipment and infrastructure[98] to administer such drugs in-office. When considering whether to provide in-office administration of such patient-specific, non-shelf-stable drugs, the practice's primary considerations should focus on potential costs incurred due to compliance with all regulations, potential space modifications, and the practicality of operating a USP 797-compliant facility within their practice.

Available financial resources

The importance of a practice's available financial resources cannot be overstated when determining whether and how to provide in-office administration of specialty drugs. The primary areas of cost consideration are acquisition, storage, preparation/administration, and disposal.

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95 In addition to state-specific laws and regulations, applicable federal laws include the Resource Conservation and Recovery Act of 1976 (42 U.S.C. §§ 6901 *et seq.*) and the Controlled Substances Act (21 U.S.C. §§ 801 *et seq.*).

96 *See ASHP Guidelines on Handling Hazardous Drugs*, 63 Am. J. Health-Sys. Pharmacy 1172, 1173 (2006) [hereinafter *ASHP Guidelines on Handling Hazardous Drugs*], *available at* www.ashp.org/DocLibrary/CE/AJHP06002.aspx (noting that the reconstituting and compounding of chemotherapeutic agents and other hazardous drugs for sterile administration (such as by infusion) is regulated by Chapter 797 of the United States Pharmacopeia ("USP 797")).

97 *See Weighing the Options for Optimal Chapter <797> Compliance*; *see also Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*, at 3–4; *CSTDs as a Cost of Doing Business.*

98 In addition to installing equipment such as pharmacy hoods, locking refrigerators and drug storage areas, and contamination cabinets, a practice may need to make structural changes, including the installation of clean rooms or other barrier isolation, the addition of specialized ventilation, and the addition of secure areas for hazardous waste collection. USP 797 compliance also requires specific types of wall surfaces, floor coverings, personal protective gear, and other items that could be contaminated by hazardous drugs. *See* U.S. Pharmacopeia, USP 797: Pharmaceutical Compounding–Sterile Preparations, *available at* www.pharmacopeia.cn/v29240/usp29nf24s0_c797_viewall.html.

Acquisition

The cost of drug acquisition uniquely affects buy-and-bill providers because white-bagged drugs have been paid for by patients and their insurers. Drug acquisition costs will be impacted by a practice's drug utilization patterns and patient volume (over which a practice has some degree of control), distribution restrictions,[99] manufacturers' drug prices, and the reimbursement policies of governmental and private payers (over which physicians have little to no control). In addition to calculating a drug's acquisition costs and reimbursement potential, a practice should consider the current and projected profit margins for the practice as a whole and whether the practice's profit margin is sufficient to accommodate occasional drug losses and changes in drug prices or reimbursement rates.[100] If drug acquisition consumes a majority of a practice's available cash, the practice could easily fall into financial trouble if the drugs are damaged, stolen, or otherwise become unusable.[101]

Storage

As discussed above, both buy-and-bill and white-bagging practices must evaluate whether they have sufficient space to safely store specialty pharmaceuticals or sufficient financial resources to acquire

99 For example, in late 2014, pharmaceutical company Genentech—maker of Avastin, Rituxan, and Herceptin—altered its distribution model, requiring purchasers to acquire these drugs from five specialty pharmacy distributors, rather than from one of 80 specialty wholesalers that had distributed the drugs previously. This added a link in the supply chain and, perhaps more importantly, eliminated the opportunity for physician practices to obtain purchasing discounts available through the wholesale market. *See* Randi Hernandez, *Ascension Health Bans Genentech Sales Reps After Losing Drug Discounts*, PharmTech.com, Oct. 7, 2014, www.pharmtech.com/ascension-health-bans-genentech-sales-reps-after-losing-drug-discounts-0 (last visited Apr. 14, 2015); *see also* Ed Silverman, *Genentech Sales Reps Face Hospital Bans Over a Wholesale Change*, WSJ Pharmalot (Oct. 3, 2014, 6:48 PM), http://blogs.wsj.com/pharmalot/2014/10/03/genentech-sales-reps-face-hospital-bans-over-a-wholesale-change/.

100 *See Business Savvy in the Age of Biologics*, at 50 (noting that profit margins are narrow, and the impact of minor drug losses can be financially significant).

101 *See Connecting Patients with Specialty Products Part 1*, at 11.

space and/or make modifications to existing space to meet drug storage requirements.

Preparation and administration

The cost of drug preparation and administration will largely depend on a practice's patterns of drug utilization. For a practice utilizing shelf-stable drugs acquired from the manufacturer in prepackaged doses, these costs will likely be relatively minimal and limited to expenses such as the cost of intravenous (I.V.) administration supplies, chairs to accommodate patients receiving I.V. medications, and perhaps, depending on the practice's volume, additional personnel dedicated to monitoring patients receiving the medications.

For a practice utilizing chemotherapy and other hazardous drugs, preparation and administration costs can be substantial given the strict regulatory controls and industry standards with which the practice must comply; additional personnel needed to prepare and/or administer the drugs; training personnel on how to safely handle and administer the medications; and the additional costs of protective gear needed for proper preparation and administration.[102] For buy-and-bill practices, some of these costs may be covered by the percentage above ASP contained in payer reimbursements.[103] White-bagging practices, however, must be able to cover these expenses using income derived from other areas.[104]

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102 *See Successful Management of a Neurology Infusion Practice*; *see also CSTDs as a Cost of Doing Business.*

103 *Examining Reforms to Improve the Medicare Part B Drug Program for Seniors*, at 3–4 (noting that, "[t]his six percent [over ASP that is paid by Medicare] is incredibly important because none of the work that must occur to prepare chemotherapy for administration to a patient is otherwise reimbursed by Medicare. . . . Even in small clinics with one or two medical oncologists, the ancillary staff to do all the above can be 4-5 highly trained professionals and in larger clinics, the staffing is accordingly much bigger."

104 *See The State of Oncology Practice*; *see also Connecting Patients with Specialty Products: Part 1*.

Disposal

A practice must consider the costs related to drug disposal when determining its financial capability of providing in-office administration of specialty pharmaceuticals. In addition to applicable state-specific laws, physician practices must comply with the requirements of the federal Resource Conservation and Recovery Act of 1976 (RCRA) when disposing of chemotherapy and other hazardous pharmaceutical waste.[105] Compliance can be costly for both buy-and-bill and white-bagging practices, but can be more significant for white-bagging practices as they are more likely to have to dispose of unused patient medications.[106] Buy-and-bill practices prepare patients' drugs from their bulk stock, using only what is needed, resulting in disposal that is often limited to trace amounts of the drug, such as the trace amounts left over in a used I.V. administration bag. Under RCRA, these empty containers with trace amounts of drugs may be disposed of as medical waste.[107] In contrast, when white-bagging practices dispose of patients' unused chemotherapy or other similar medications, they must comply with more costly hazardous waste disposal and documentation requirements in accordance with regulations established by the Environmental Protection Agency.[108]

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105 *See* U.S. Envtl. Prot. Agency, *Management of Hazardous Waste Pharmaceuticals*, http://epa.gov/wastes/hazard/generation/pharmaceuticals.htm (last visited Apr. 14, 2015) for guidance documents and list of federal regulations governing disposal of hazardous waste pharmaceuticals; *see also* Madison Envtl. Resourcing, Inc., *10 Costly Mistakes Facilities Make During Pharmaceutical Waste Disposal*, MERI's Blog (Dec. 2, 2014) [hereinafter *10 Costly Mistakes Facilities Make During Pharmaceutical Waste Disposal*], www.meriinc.com/blog/10-costly-mistakes-facilities-make-pharmaceutical-waste-disposal/#sthash.geGvQQvB.dpbs (noting the significant fines that may be levied by the EPA for noncompliance with disposal requirements).

106 *See Challenging New Delivery Models for Injectable Drugs*, at 9 (discussing the volume of unused patient medications often seen with white-bagging, and noting that practices must dispose of these medications at their own expense).

107 *See ASHP Guidelines on Handling Hazardous Drugs*, at 1184.

108 *See id.* at 1184–85; *see also 10 Costly Mistakes Facilities Make During Pharmaceutical Waste Disposal*.

Conclusion

The field of specialty pharmaceuticals is expanding rapidly, giving physicians and patients an ever-increasing number of treatment options for managing and even curing once-untreatable conditions. The rules for acquiring and administering these drugs, however, are also constantly changing. Physicians who want to provide in-office administration for their patients should consider their drug acquisition options, taking into consideration their areas of medical specialty, patterns of drug utilization, patient-payer mix, physical space, and the impact of each of these factors on available financial resources before deciding whether and how to provide their patients with in-office administration of specialty pharmaceuticals.