Hospital Outpatient vs. Office Outpatient

Venus & Mars?

by Teri Guidi, MBA, FAAMA

Listserves for cancer program and practice administrators are often filled with questions about rules and regulations: physician oversight, facility fees, employee safety, and more. Well-meaning colleagues are always generous with their answers. Unfortunately, the answers are sometimes slightly erroneous because the respondent is familiar with one care setting while the query emanated from another setting. This article offers an overview of the main differences in rules and regulations as they apply to the hospital outpatient department (HOPD) and the physician office setting (POS).

For the purposes of this article, we define the HOPD as an infusion clinic or center operating under a hospital's license, whether for-profit or non-profit, and the POS as a physician office or infusion center operating under a physician's medical license. Another model is hospital-owned clinics referred to as "provider-based" clinics. These are outpatient centers operating under a hospital's license but not co-located with the hospital. The HOPD (and hospital-owned provider-based clinics) bill infusion services and drugs on CMS 1450 forms, also referred to as "UB-04s" (bill type 13x), while the POS bills on CMS 1500 forms.

Oversights and Inspections

Numerous federal, state, and local agencies are tasked with ensuring safety. Among those likely to apply to outpatient infusion services are

- The Occupational Safety and Health Administration (OSHA)
- The United States Pharmacopeia (USP)
- Local and state Departments of Health (DOH)
- Various Boards such as the Board of Medicine, Board of Pharmacy, Board of Nursing, etc.
- The Joint Commission.

OSHA. This federal agency is charged with the enforcement of safety and health legislation. OSHA occasionally performs announced and unannounced visits to institutions, but rarely to physician offices. Visits are often prompted by a safety complaint lodged by employees or patients. Both the HOPD and the POS are subject to OSHA policies.

USP. This federal organization is the standards-setting authority for all prescription and over-the-counter medicines. Recently, USP Chapter 797 has become a major topic of discussion because these standards may require significant changes to pharmacy departments and/or drug mixing areas. The American Society of Health-System Pharmacists (ASHP) has issued extensive opinion on this topic (*www.ashp.org*). By definition, both the HOPD and the POS are subject to the standards, although the mechanism for enforcement is unclear. In the POS setting, adherence to these standards may be difficult to meet due to the associated expense with facility and equipment requirements.

DOH. These agencies are also charged with ensuring the safe delivery of health care. Policies differ from one DOH to another, and requirements may differ from HOPD to POS. Good examples include requirements for exam room, infusion bay, and hallway sizes.

Medicine, Nursing, and Pharmacy Boards. As with the DOH, each Board sets its own rules and regulations and the authority of each differs from state to state. These rules and regulations apply to individuals—regardless of the care setting (HOPD or POS).

The Joint Commission. An independent, not-for-profit organization that accredits and certifies healthcare organizations and programs, The Joint Commission performs both announced and unannounced surveys at accredited institutions. Accreditation is voluntary, and presently no accreditation category is applicable to the POS. In some circumstances, however, the Joint Commission may visit a POS. For example, a health-system-owned physician practice co-located with the HOPD might be visited. In these situations, the hospital needs to explain the organizational structure and licensure that may exempt the practice from Joint Commission examination. Most institutions with this scenario prefer to ensure that the practice is compliant in order to avoid possible problems.

Medicare Coverage

The Medicare program separates benefits into several categories called "Parts." The two main categories applicable to outpatient infusion are Part A and Part B coverage. Part A benefits cover "hospital" inpatient services including:

- Inpatient care
- Skilled Nursing Facility (SNF) care
- Hospice and home care
- Blood.

Part B benefits cover medical and "outpatient" services including:

- Non-routine physician services
- Laboratory tests and services
- Home care services
- Hospital outpatient services (including outpatient infusion)
- Blood transfusions.

Thus Medicare payment for outpatient chemotherapy infusions falls under the Part B benefit, whether administered in the HOPD or the POS. Despite this common funding source, until recently all hospital claims, Part A and Part B, were processed by a "fiscal intermediary" dealing exclusively with hospital claims. And all POS claims were processed by a "carrier" dealing with physician office claims.

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Under Medicare contracting reform, the Centers for Medicare & Medicaid Services (CMS) is in the process of combining fiscal intermediary and carrier functions under Medicare Administrative Contractors or MACs, which will administer both Part A and Part B claims.

Administration of Infusion Services

Somewhat surprising to many is the fact that while the same part of Medicare (Part B) pays for outpatient infusions and drugs in both the HOPD and the POS, payment amounts are different in the two settings.

In the HOPD, payments are set using CMS's Hospital Outpatient Prospective Payment System (HOPPS), which groups various items (CPT codes, HCPCS codes) into Ambulatory Payment Classifications (APCs). One APC may include numerous CPT codes, and all codes assigned to that APC are paid at the same rate. For example, CPT codes 96360 (IV hydration 31-60 minutes), 96411 (Chemotherapy push), and 96417 (Chemotherapy, IV sequential infusion up to 1 hour) are all assigned to APC 0438 and are all paid at $73.67 (national figure, not geographically adjusted). Annually, CMS reviews the assignment of CPT and HCPCS codes to APCs and frequently makes changes. Changes appear each year in the proposed HOPPS rule, which is usually published in August. With the release of the final HOPPS rule, the proposed changes are finalized. For example, CMS released the 2009 final HOPPS rule October 30, 2008, and the final rule took effect on January 1, 2009.

CMS establishes the payment rates for services (e.g., infusions and injections) using complicated calculations that are primarily based on hospitals' costs. The agency determines these costs by applying hospital-reported cost-to-charge ratios to hospital charges. Adjustments for geographic cost-of-living variations are also applied in calculating the final payment amount.

In the POS, the fee schedule for infusion and injection services are set using the American Medical Association's Relative Value Units (RVUs), to which CMS applies an annually updated conversion factor. Adjustments for geographic cost-of-living variations are also applied. Table 1 shows a comparison of payment rates for selected administration codes in the HOPD and POS.

Pharmaceuticals

Payment for drugs also differs in the two care settings. Legislation requires CMS to pay for certain drugs and biologics (largely oncology infusion and/or injection drugs) at 106 percent of Average Sales Price (ASP) in the POS. However, that same legislated rate does not uniformly apply in the HOPD. For 2009, in the HOPD, drugs with "pass through" status are paid at 106 percent of ASP, and drugs that are no longer on "pass through" status are paid at 104 percent of ASP. "Low-cost" drugs are not paid separately at all. They are considered "packaged" into the payment for administration. Currently "low cost" includes drugs that CMS estimates cost less than $60 per day.

In both the HOPD and POS setting, payment rates for separately payable drugs are updated quarterly based on manufacturer reporting of sales data. Also in both settings, approval for payment may be denied if the claims administrator (Fiscal Intermediary, Carrier, or A/B MAC) determines that medical necessity is not met. Determination of medical necessity sometimes differs for the two settings although the move to MACs should eliminate these inconsistencies.

Documentation and Supervision

Regardless of care setting, documentation of medical necessity and of care delivered is required. This documentation must be part of the provider's medical record or chart. For the POS, this requirement is relatively straightforward and does not present significant challenges. For the HOPD, it is more complicated because much of the "source documentation" may reside in the POS chart rather than in the hospital's records. In particular, physician dictations and documentation of a physician's diagnosis are not necessarily available in the hospital chart, making documentation of medical necessity difficult to demonstrate in the face of an audit.

In late 2008, CMS released clarifications regarding the physician supervision requirements. And while it has long been clear that a "provider-based" clinic must have a physician in attendance to meet the requirements, questions remain despite the clarifications. For example:

- *What is the definition of "on the premises?"* Many practices have space on two floors of a single building (different suite numbers). Is each suite to be considered its own premises?
- *What is the definition of "present and immediately available?"* Few HOPDs are co-located with the ordering physician offices and, even in provider-based clinics, the physicians may be located several floors, suites, or miles away from the infusion suite. CMS's clarifications have attempted to address this question, but many continue to struggle with the concept. For example, if the infusion suite is self-contained and employed physicians are in the clinic space next door, is that sufficient? What if those physicians are not employed but lease space in the next suite or one floor above?
- *Does CMS intend to further tighten the requirements to place a physician of the applicable discipline or specialty "on the premises and immediately available?"*

The first two questions are difficult to answer and require consideration by your compliance office and/or legal counsel at least until CMS provides sufficient examples to cover all scenarios. The last question also requires some thought. The Oncology Management Consulting Group believes that since CMS repeatedly refers to safety as one of the main reasons for the requirements, then eventually the agency will further tighten the definition of the appropriate physician available to supervise care. In general, we also believe hospitals and practices should err on the side of conservatism. In other words, if you are questioning the requirement, assume the most restrictive interpretation possible.

Purchasing Drugs

Oncology drugs constitute a major component of total pharmacy expenses in the hospital, and national figures estimate that drug cost represents more than 60 percent of total POS expenses. There are purchasing groups for hospitals and there are purchasing groups for physician practices. The distinctions are, in part, the result of the Robinson-Patman Act of 1936 (and the subsequent Non-Profit Institutions Act of 1938). These Acts address issues

of pricing, effectively forbidding a seller from offering differential or preferential pricing on the same goods and services to comparably qualified buyers. Often referred to as "class of trade," the distinctions may result in different purchase prices for POS than for HOPDs. We have often heard physicians complain that hospitals obtain better pricing for drugs. In our experience, however, neither the hospital nor the POS consistently receive better purchase prices for oncology drugs, largely because the manufacturers do not offer significant breaks for either class of trade.

The 340B federal pricing program offers the best pricing for virtually all drugs available within the program. This program is open only to institutions (hospitals) and only to those that meet participation criteria. The criteria relate largely to the proportion of uncompensated care provided. Further, drugs acquired at 340B prices may only be used for the hospital's own outpatients—no inpatient use, no dispensing from a retail pharmacy, no resale to other providers. Participation in the 340B program is not available to the POS.

As cost and reimbursement pressures continue to rise, there is also an increase in the number of hospitals and oncology physician practices considering new organizational models. As those models are explored, it is important to understand the various differences between the two care settings in order to avoid making decisions that are based on inaccurate assumptions.

Teri Guidi, MBA, FAAMA, is president and CEO of the Oncology Management Consulting Group.

Table 1. 2009 CMS National Payment Rates for Selected Chemotherapy Administration Codes

Code	Code Descriptions	HOPD	POS
96360	IV, hydration; initial, 31 minutes to 1 hour (not for < 30 minutes)	$73.67	$56.62
96361	IV, hydration; each additional hour (this follows any initial through same IV access)	$24.89	$16.59
96365	Therapeutic IV; initial, up to 1 hour	$128.62	$68.89
96366	Therapeutic IV; each additional hour	$24.89	$22.00
96367	Therapeutic IV; additional sequential infusion, up to 1 hour (only once for same infusate mix)	$36.13	$34.62
96368	Therapeutic IV; concurrent infusion (only 1 per encounter)	$0.00	$20.56
C8957	Therapeutic IV; initiation of prolonged infusion (> 8 hours), requiring portable or implantable pump	$187.96	$0.00
96369	SQ infusion for therapy; initial, up to one hour, including pump set-up and establishment of SQ infusion site(s)	$73.67	$149.68
96370	SQ infusion for therapy or prophylaxis; each additional hour	$36.13	$15.87
96371	SQ infusion for therapy or prophylaxis; additional pump set-up with establishment of new SQ infusion site(s)	$24.89	$72.49
96372	Therapeutic injection; subcutaneous or intramuscular (in offices only if physician is in suite)	$24.89	$20.92
96373	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intra-arterial	$36.13	$18.03
96374	Therapeutic push, single or initial substance/drug	$36.13	$54.46
96375	Therapeutic push, each additional sequential intravenous push of a new substance and/or drug	$36.13	$23.80
96376	Therapeutic push, each additional sequential intravenous push of a new substance and/or drug provided in a facility. Do not report 96376 for a push performed within 30 minutes of a reported push of the same substance or drug. 96376 may be reported by facilities only.	$0.00	$0.00
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion	$24.89	$0.00
96401	Chemotherapy SQ or IM non-hormonal anti-neoplastic	$36.13	$67.44
96402	Chemotherapy SQ or IM hormonal anti-neoplastic	$36.13	$36.79
96409	Chemotherapy push technique; single or initial substance and/or drug	$128.62	$111.81
96411	Chemotherapy push technique; each additional substance and/or drug	$73.67	$63.84
96413	Chemotherapy IV up to 1 hour; single or initial substance and/or drug	$187.96	$147.51
96415	Chemotherapy IV technique; each additional hour	$36.13	$33.54
96416	Chemotherapy IV technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	$187.96	$160.86
96417	Chemotherapy IV technique; each additional sequential infusion (different substance and/or drug), up to 1 hour	$73.67	$73.58
96521	Refilling and maintenance of portable pump	$187.96	$126.95
96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g, intravenous, intra-arterial)	$128.62	$107.84
96523	Irrigation of implanted venous access device for drug delivery systems. Do not report 96523 if any other services are provided on the same day.	$39.92	$25.25