



INFUSION SUITES: HOW TO PROPERLY SET UP & OPERATE

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BACKGROUND

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- Increased popularity in recent years in the creation and use of infusion suites.
- Infusion services may be provided by a variety of health care providers.
 - Physicians, Nurse Practitioners, Hospitals, Pharmacies, etc.
- Given this collaboration by health care providers, it is important that arrangements for infusion suites are carefully structured in compliance with federal and state laws as well as payor requirements.

TYPICAL SET UP

- Physician/Physician Group owns and operates an infusion suite in the Physician/Physician Group's office(s).
- Pharmacy provides infusion drugs and supplies and limited other services to health care providers.
- In order to facilitate the provision of care to its patients, Physician/Physician Group contracts with Pharmacy for the provision of drugs and for the furnishing of specified services for the infusion suite.



INFUSION SUITE MANAGEMENT AGREEMENTS

INFUSION SUITE MANAGEMENT AGREEMENTS

- Services Provided by Pharmacy
 - Provision of Drugs
 - Pharmacy shall be the sole and exclusive provider for drugs and supplies obtained by the Physician/Physician Group for operations of the infusion suite.

INFUSION SUITE MANAGEMENT AGREEMENTS

- Exceptions
 - Pharmacy advises the Physician/Physician Group that Pharmacy cannot provide the requested drug or supply.
 - The parties mutually agree to an alternate purchase arrangement.
 - Use of pharmacy is contrary to patient's choice.
 - Applicable law requires a different arrangement.

INFUSION SUITE MANAGEMENT AGREEMENTS

- Administrative and Reimbursement Services
 - Periodic reports of revenue and expenses of the infusion suite
 - Verification of insurance coverage
 - Claims billing and collection services
 - Staffing services

INFUSION SUITE MANAGEMENT AGREEMENTS

- Pharmacy's Duties and Responsibilities
 - Maintain applicable licenses and accreditation.
 - Operate within the scope of practice.
 - Maintain professional and general liability insurances.
 - Representations and warranties of no exclusions from participation in federal health care programs or state health care programs.

INFUSION SUITE MANAGEMENT AGREEMENTS

- Infusion Suite's Duties and Responsibilities
 - Furnish and maintain space and equipment that is safe, clean, free of hazards and adequate for the operation of an infusion suite.
 - Staffing of clinical and non-clinical personnel.
 - Supervision of medical and health care services provided at infusion suite.
 - Maintain applicable licenses, accreditation and insurance coverage.
 - Representations and warranties of no exclusions from participation in federal health care programs or state health care programs.

INFUSION SUITE MANAGEMENT AGREEMENTS

- Compensation and Financial Records
 - Fee Schedule for the purchase of drugs.
 - Compensation for other services provided.
- Non-Solicitation
- Non-Disclosure and Confidentiality

INFUSION SUITE MANAGEMENT AGREEMENTS

- Indemnification
- Term and Termination
 - Term of at least 1 year
 - Provisions regarding breaches
- Business Associate Agreement



FRAUD & ABUSE ISSUES

FRAUD & ABUSE ISSUES - FEDERAL ANTI-KICKBACK STATUTE

- Federal Anti-Kickback Statute
 - Prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.
 - Prohibits remuneration if “one purpose” is to induce or reward referrals, even if the remuneration is for other appropriate purposes.
 - State counterparts, which may be broader or more restrictive than the federal statute, may be applicable.

FRAUD & ABUSE ISSUES - FEDERAL ANTI-KICKBACK STATUTE

- Important Questions to Ask
 - Are the parties in a position to refer patients to each other?
 - E.g., referrals from the owners of or the physicians providing services at the infusion suite to the pharmacy
 - Is remuneration being exchanged between the parties?
 - E.g., payment from the owners of the infusion suite to the pharmacy for the pharmacy's services
 - Is the remuneration fair market value, commercially reasonable for the services being rendered?
 - E.g., what would you pay for the services if the other party does not refer patients to you?

FRAUD & ABUSE ISSUES - FEDERAL ANTI-KICKBACK STATUTE

- Important Questions to Ask (cont'd)
 - Is there an applicable safe harbor?
 - E.g., Personal Services and Management Contracts safe harbor
 - Does the arrangement comply with guidance issued by the Office of Inspector General (“OIG”)?
 - OIG advisory opinions, special fraud alerts, special advisory bulletins

FRAUD & ABUSE ISSUES - FEDERAL ANTI-KICKBACK STATUTE

- Personal Services and Management Contracts Safe Harbor Requirements
 - The agreement is set out in writing and signed by the parties;
 - The agreement covers all of the services to be provided for the term of the agreement and specifies the services to be provided;
 - If the services are to be provided on a periodic, sporadic or part-time basis, the agreement specifies the schedule of such intervals, their precise length, and the exact charge for such intervals;
 - The term of the agreement is for not less than one year;

FRAUD & ABUSE ISSUES - FEDERAL ANTI-KICKBACK STATUTE

- Personal Services and Management Contracts Safe Harbor Requirements (cont'd)
 - The aggregate compensation is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under federal health care programs;

FRAUD & ABUSE ISSUES - FEDERAL ANTI-KICKBACK STATUTE

- Personal Services and Management Contracts Safe Harbor Requirements (cont'd)
 - The services performed do not involve the counselling or promotion of a business arrangement or other activity that violates any state or federal law; and
 - The aggregate services do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

FRAUD & ABUSE ISSUES - STARK LAW

- Stark Law
 - A “physician may not make a referral to [an] entity for the furnishing of designated health services” if the “physician (or an immediate family member of such physician) has a financial relationship with [such] entity,” unless a Stark Law exception is met.
 - The Stark Law is a strict liability statute.
 - There may also be state laws that restrict or prohibit physician self-referrals.

FRAUD & ABUSE ISSUES - STARK LAW

- Important Questions to Ask
 - Is there a financial relationship between the pharmacy and the physician, the physician group or an immediate family member of the physician?
 - May be an ownership interest or a compensation arrangement.
 - Is there a referral?
 - A “referral” includes a “request by a physician for, or ordering of ... any designated health service for which payment may be made under” Medicare and Medicaid.

FRAUD & ABUSE ISSUES - STARK LAW

- Important Questions to Ask (cont'd)
 - Are designated health services (“DHS”) being referred?
 - May be an ownership interest or a compensation arrangement.
 - Does a Stark Law exception apply?
 - E.g., In-Office Ancillary Exception.

FRAUD & ABUSE ISSUES - STARK LAW

- In-Office Ancillary Exception
 - Detailed requirements regarding
 - Furnishing of DHS
 - Must be done by the referring physician, a physician who is a member of the same group practice as the referring physician or an individual who is supervised by such individuals.
 - Location of DHS services
 - Same building test vs. centralized building test.

FRAUD & ABUSE ISSUES - STARK LAW

- Billing for DHS
 - Physician performing or supervising the service.
 - The group practice.
 - An entity that is wholly owned by the performing or supervising physician or by that physician's group practice.
 - An independent third-party billing company acting as an agent.



MEDICARE BILLING & REIMBURSEMENT

MEDICARE BILLING & REIMBURSEMENT

- Drugs
 - Medicare provides limited benefits for outpatient drugs.
 - Statutorily Covered
 - DME Supply Drugs
 - Immunosuppressive Drugs
 - Hemophilia Clotting Factors
 - Oral Anti-Cancer Drugs
 - Oral Anti-Emetic Drugs
 - Pneumococcal Vaccine
 - Hepatitis B Vaccine
 - Influenza Vaccine
 - Antigens

MEDICARE BILLING & REIMBURSEMENT

- Statutorily Covered (cont'd)
 - Erythropoiesis-stimulating Agent
 - Parenteral Nutrition
 - Intravenous Immune Globulin Provided in the Home
- Covered In the Context of a Professional Service
 - Drugs Furnished “Incident to” a Physician Service
 - Separately Billable Drugs Provided in Hospital Outpatient Departments
 - Drugs Covered as Supplies or “Integral to a Procedure”
 - Blood
 - Drugs Furnished as Part of a Service in Provider Settings

MEDICARE BILLING & REIMBURSEMENT

- Pharmacies may bill Medicare Part B for certain classes of drugs (immunosuppressive drugs, oral anti-emetic drugs, oral anti-cancer drugs, and drugs self-administered through any piece of DME).
 - Claims should be submitted to the DME MAC.
- Pharmacy dispenses a drug that will be administered through implanted DME and a physician's service will not be utilized to fill the pump with the drug.
 - Claims should be submitted to the A/B MAC.

MEDICARE BILLING & REIMBURSEMENT

- Pharmacies may not bill Medicare Part B for drugs furnished to a physician for administration to a Medicare beneficiary.
 - When these drugs are administered in the physician's office to a beneficiary, the drugs are being administered "incident to" a physician's service.
 - The only way these drugs can be billed to Medicare is if the physician purchases the drugs from the pharmacy.
- Pharmacies may not bill Medicare Part B for drugs dispensed directly to a beneficiary for administration "incident to" a physician service.
 - E.g., refilling an implanted drug pump.

MEDICARE BILLING & REIMBURSEMENT

- “Incident to” Billing
 - Medicare pays for services and supplies provided “incident to” the service of a physician (or other practitioner).
 - Requirements
 - Services and supplies must be furnished in a non-institutional setting to non-institutional patients.
 - Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
 - Services must be part of the patient’s normal course of treatment during which a physician personally performed an initial service and remains actively involved in the course of treatment.

MEDICARE BILLING & REIMBURSEMENT

- Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).
 - The cost of the drug or biological must represent an expense to the physician.
 - Implications for pharmacy billing for infusion drugs administered in a physician's office.
 - Pharmacies may not supply the infusion drugs to the physician without requiring payment.
- Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

MEDICARE BILLING & REIMBURSEMENT

- In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner).
 - “Direct supervision” in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.
 - It does not mean that the physician must be present in the room when the procedure is performed.
 - Audio/visual monitoring from a remote location is not sufficient.

MEDICARE BILLING & REIMBURSEMENT

- Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.
- A physician (or other practitioner) may be an employee or an independent contractor.
- Drugs must be of a form that is not usually self-administered.

MEDICARE BILLING & REIMBURSEMENT

- Reimbursement for Administration/Services
 - There are few occasions when an office may bill for the administration of a drug only.
 - E.g., Patients supplying their own drugs for administration in a suite or office.
 - Providers are prohibited from instructing patients to purchase the drug themselves and then bring them to the provider's office for administration.
 - Per 2015 Noridian Healthcare Solution guidance, if the drug is not supplied as a donation or free of charge, then the provider must provide the drug under the “incident to” guidelines.



USE OF NURSE PRACTITIONERS

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- Must be furnished and utilized in accordance with state licensing laws.
 - Scope of Practice
 - Prescriptive Authority
 - Written Protocol/Physician Supervision vs. Independence

USE OF NURSE PRACTITIONERS

- Compliance with Medicare’s “Incident to” Requirements for Auxiliary Personnel
 - A Nurse Practitioner's services may be reimbursable by Medicare as “incident to” a physician’s service.
 - Under Medicare’s “Incident to” rules, drugs must be administered by the physician, or by “auxiliary personnel” employed by the physician and under the physician’s personal supervision.
 - Medicare Benefit Policy Manual, Chapter 15, Section 50.3.

USE OF NURSE PRACTITIONERS

- Definition of “auxiliary personnel”
 - Any individual who is acting under the supervision of a physician (or other practitioner).
 - Regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner).
 - Has not been excluded from the Medicare, Medicaid and all other federally funded health care programs or had his or her Medicare enrollment revoked.
 - Meets applicable requirements to provide incident to services, including licensure, imposed by the state in which the services are being furnished.



21ST CENTURY CURES ACT

21ST CENTURY CURES ACT

- Changes the reimbursement methodology for infusion drugs administered through an item of DME.
- Previously paid according to Average Wholesale Price.
 - Compared to reimbursement for most other Medicare Part B drugs which was set at Average Sales Price plus 6 percent.
 - New reimbursement based on Average Sales Price plus 6 percent.
- Intended to reflect actual transaction prices and prevent over- and underpayment of certain drugs.

21ST CENTURY CURES ACT

- Excludes infusion drugs furnished through DME from the competitive bidding program.
- Adds Medicare coverage of home infusion therapy, effective January 1, 2021, in order to “better reflect the totality of servicing beneficiaries”.



QUESTIONS?





THANK YOU

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