

# The National Medicare Prescription Drug Congress

## Exploring the Interaction between Medicare Part B and Medicare Part D

Jennifer Breuer, Esq.  
Gardner, Carton & Douglas  
191 N. Wacker Drive  
Chicago, IL 60606  
312/569-1256  
jbreuer@gcd.com

Holley Thames Lutz, Esq.  
Gardner, Carton & Douglas  
1301 K. Street N.W.  
Washington, DC, 20005  
202/230-5126  
hlutz@gcd.com

Chris Mancill, MA  
PAREXEL International  
5870 Trinity Parkway  
Centreville, VA 20120  
703/310-2046  
chris.mancill@parexel.com

# Medicare Prescription Drug Benefit: Part D

# Medicare Part D will provide Rx assistance to seniors beginning in 2006

- Part D will cover:
  - ▶ Insulin, vaccines, biologics and other medically-necessary drugs not covered under Part B
  - ▶ Must be:
    - Dispensed according to an Rx
    - Administered on an outpatient basis
    - Currently covered by Medicaid

# Part D Standard Benefit

- \$250 annual deductible
  - 25% co-pay from \$250 to \$2,250
  - 100% co-pay up to \$3,600 out-of-pocket limit
  - 5% co-pay after \$3,600
- 
- Plans may substitute cost-sharing or tiered co-pay system as long as substitute is actuarially consistent with 25% cost sharing requirement of the Standard Benefit

# Part D Low Income Benefit

- <135% FPL
  - ▶ No deductible or premium
  - ▶ \$2 (generic)/\$5 (brand) co-pay to catastrophic limit
  - ▶ No co-pay above catastrophic limit
- <150% FPL
  - ▶ \$50 deductible
  - ▶ Sliding scale premium subsidies
  - ▶ 15% co-pay up to catastrophic limit
  - ▶ \$2-\$5 co-pay above catastrophic limit

# Part D Dual Eligible Benefit

- Seniors at <100% FPL covered under Part D
  - ▶ No premiums or deductibles
  - ▶ \$1-\$3 co-pay up to catastrophic limit
  - ▶ No co-pay above catastrophic limit
- States must make monthly premium/cost sharing payments to Part D to cover the costs of Rx drugs for dual eligibles
- Part D low income assistance reduces demand for State- and manufacturer-sponsored patient assistance programs

# Part D coverage will be administered through private payors

- To access Part D coverage, beneficiaries must purchase coverage from:
  - ▶ Prescription Drug Plans (PDP)
    - Drug-only plan for traditional FFS Medicare beneficiaries
  - ▶ Medicare Advantage
    - PPO/HMO integrated health and drug benefit
- PDPs will operate like commercial insurers
  - ▶ Negotiate discounts with manufacturers/PBMs
  - ▶ But, all discounts must be passed through to beneficiaries

# PDP Requirements

- PDPs may develop formularies
  - ▶ PDPs must offer at least one drug in each therapeutic class (as established by USP)
    - Formulary must be developed and reviewed by P&T Committee
    - PDPs must notify HHS, pharmacies, providers and beneficiaries of changes in formulary
  - ▶ Depending on the number of PDPs available in any geographic area, coverage of any particular brand of drug may not be available
  - ▶ Beneficiaries may appeal a denial in coverage
  - ▶ Need not pay for any off-formulary Rx

# HHS Will Provide Financial Support to PDPs

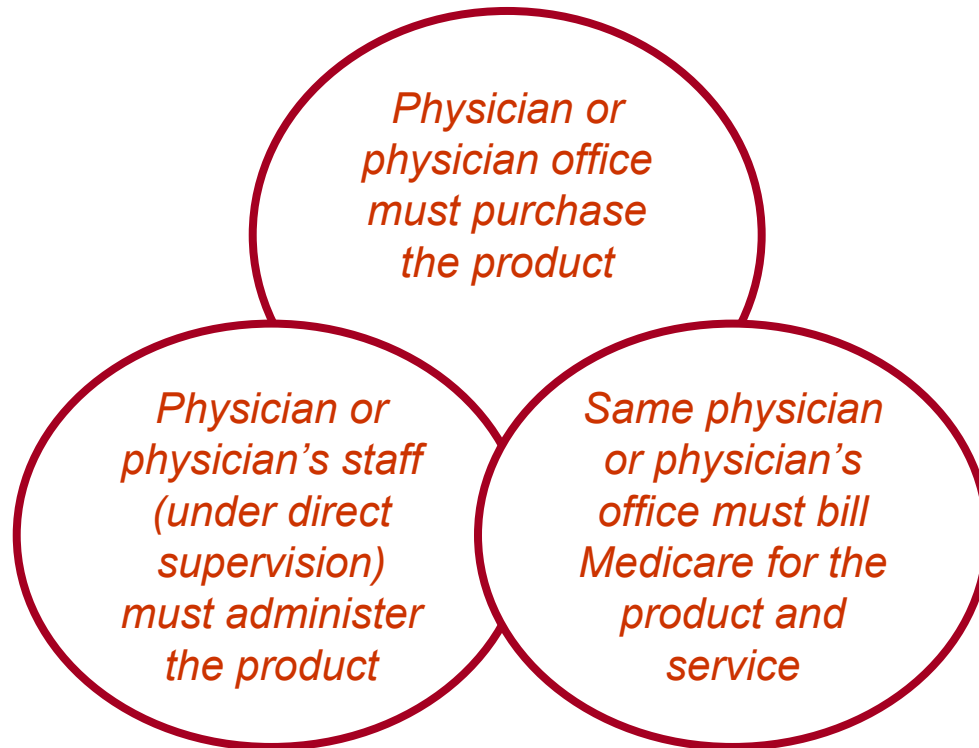
- The Act establishes a Medicare Rx Drug Account in the Part B Trust Fund. Will be used to pay:
  - ▶ Low-income premium subsidies
  - ▶ Direct subsidy payments to PDPs
  - ▶ Reinsurance amounts
  - ▶ Subsidies to retiree Rx drug plans
  - ▶ Medicaid programs for increased administrative expenses

# Medicare Prescription Drug Benefit: Part B

# Through 2006, Part B will continue to cover certain drugs and biologics

- Part B covered drugs and biologics must:
  - ▶ Meet the definition of drugs and biologics
  - ▶ Not be self-administered
  - ▶ Meet all “incident to a physician service” coverage requirements
  - ▶ Be reasonable and necessary for the purpose for which they are administered, according to accepted medical practice
  - ▶ Not be excluded as immunizations
  - ▶ Not have been determined by FDA to be less than effective

# To qualify for Part B coverage, drugs and biologics must be administered incident to a physician service



Drugs and biologics also must be medically necessary for the indications for which they are administered

# Certain other drugs and biologics also qualify for Part B coverage

- Immunosuppressive agents
- Home coverage of antihemophilia clotting factors
- Certain oral anti-cancer drugs
- Oral anti-emetics
- Pneumococcal, influenza, and hepatitis vaccines
- Antigens
- Home coverage IGIV for primary immune deficiencies
- EPO for home dialysis patients
- Other drugs separately billed by ESRD treatment facilities
- Certain osteoporosis drugs

# The Act includes certain changes to traditional Part B coverage

- Through December 2004, most Part B drugs will be reimbursed at 85% of AWP
  - ▶ Until now, reimbursed at 95% of AWP
  - ▶ Some products reimbursed at as low as 80% of AWP
- Effective January 2005, most Part B drugs will be reimbursed using an average sales price (ASP) methodology
- Effective January 2006, CMS will phase-in a competitive acquisition program (CAP)

# Move from AWP to ASP, CAP intended to combat “waste, fraud and abuse”

- AWP-based payment methodology widely criticized as providing excessive margins to providers and suppliers
- But physicians argue that margins are required to make up for inadequate reimbursement for professional services associated with drug administration
  - ▶ Act increases reimbursement for professional service component of administration

# Average Sales Price

- ASP will be calculated by NDC on a quarterly basis by dividing each manufacturer's total sales by the total number of units sold
  - ▶ ASP will take into account all package sizes as well as discounts, chargebacks and rebates
  - ▶ ASP will not take into account Medicaid rebates, sales exempt from the Medicaid drug rebate program and sales that are nominal in amount
- Part B drugs will be reimbursed at 106% of ASP
  - ▶ ASP takes into account discounts that may not be available to a particular provider
  - ▶ Thus, MD reimbursement may be disproportionate to MD costs

# Manufacturers must report ASP to HHS

- To obtain coverage, manufacturers must report quarterly information on ASP
  - ▶ Total number of units sold
  - ▶ Wholesale acquisition cost
  - ▶ Sales made at a nominal price
- IG will monitor “widely available market price”
  - ▶ Price prudent buyer would pay, taking into account discounts, rebates, routine price concessions
- If reported ASP > WAMP by 5% (in 2005), HHS may disregard ASP
  - ▶ HHS may adjust price to the lower of WAMP or 103% of Medicaid average manufacturer’s price

# Manufacturers who report false ASP information are subject to liability

- Act makes the knowing submission of false information regarding ASP a “false record or statement ... used to get a false or fraudulent claim approved by the government” in violation of the False Claims Act (31 U.S.C. § 3729 *et seq.*)
- In addition, manufacturers who misrepresent ASP may be fined up to \$10,000 per discrepancy per day the false price applies

# Competitive Acquisition Program (1)

- Beginning in 2006, CAP will provide an alternative for MDs who do not wish to provide Part B drugs for ASP reimbursement
  - ▶ MDs may enroll in a CAP on an annual basis
- Instead, a contractor will deliver the covered drug/biologic to the MD
- The contractor will bill for the drug/biologic after it is administered, collecting reimbursement from PDP and deductibles from the beneficiary

# Competitive Acquisition Program (2)

- In order to implement the CAP, HHS will establish “competitive acquisition areas” throughout the US
- HHS will conduct a competition among entities able to provide drugs/biologics within each category of HCPCS code to physician offices within each geographic area
  - ▶ HHS may limit the number of entrants in each area, but not below two
  - ▶ Contracts will be awarded based on bid price and ability to meet certain other requirements

# Competitive Acquisition Program (3)

- Chosen contractors will supply drugs/biologics upon receipt of an Rx, submit claims for reimbursement and collect all deductibles and co-pays
- Medicare will reimburse at 80% of accepted bid price, after the beneficiary meets the applicable deductible
  - ▶ HHS will establish a single payment amount for each drug in each geographic area

# Competitive Acquisition Program (4)

- The CAP methodology may lead to increased use of formularies
- Each contractor must provide only one drug within each HCPCS code within each geographic area
  - ▶ Multiple source drugs and generics are therapeutically equivalent
  - ▶ HHS may limit the number of contractors to which it awards contracts (but not below two)
  - ▶ The result may be that not all brands or products are available within any geographic area

# Certain Part B drugs/biologics receive special treatment under the Act (1)

- Blood clotting factors
  - ▶ HHS must review GAO report and devise an appropriate payment methodology
- Immunosuppressive and anti-cancer agents
  - ▶ CMS must pay a dispensing fee to pharmacies that provide chemotherapy
  - ▶ No fee will be paid when payment is made under the ASP or CAP methodologies
- Radiopharmaceuticals
  - ▶ No change to current Part B reimbursement

# Certain Part B drugs/biologics receive special treatment under the Act (2)

- Inhalation drugs
  - ▶ In 2004, drugs dispensed through DME will be reimbursed at 85% of AWP
  - ▶ In 2005, payment will be made under ASP methodology
  - ▶ GAO must report to Congress on the adequacy of reimbursement for inhalation therapy products

<b>Part B Reimbursement for 2004</b>	
<i>Drug/Biologic Description</i>	<i>Payment Methodology</i>
General Rule for Part B Drugs, Including But Not Limited To: <ul style="list-style-type: none"> <li>• Inhalation drugs through DME</li> <li>• IVIG</li> </ul>	85% of AWP as of 4/1/2003
Carve-Outs <ul style="list-style-type: none"> <li>• Pneumococcal, flu and Hep B vaccine</li> <li>• Infusion drugs through implanted DME</li> <li>• Blood and blood products (not clotting factor)</li> <li>• Radiopharmaceuticals</li> <li>• Blood clotting factor</li> <li>• “New drugs” – no HCPCS but approved by FDA after 4/1/2003</li> <li>• Drugs and biologics furnished in connection with renal dialysis (but not EPO)</li> </ul>	<ul style="list-style-type: none"> <li>• 95% of AWP</li> <li>• 95% of AWP of 10/1/2003</li> <li>• Amount determined in same way as 10/1/2003</li> <li>• Same as 2003</li> <li>• 95% of AWP</li> <li>• 95% of AWP</li> <li>• 95% of AWP</li> </ul>

<b>Part B Reimbursement for 2005</b>	
<i>Drug/Biologic Description</i>	<i>Payment Methodology</i>
General Rule for Part B, Including But Not Limited To: •Inhalation drugs through DME •IVIG	•Single source = 106% of the lesser of : WAC or ASP •Multi-source = 106% of the volume-weighted ASPs of all drugs represented by a multi-source code <sup>[1]</sup> Or CAP
Carve-Outs •Pneumococcal, flu and Hep B vaccine •Infusion drugs through implanted DME •Blood and blood products (not clotting factor) •Radiopharmaceuticals	•95% of AWP •95% of AWP •Amount determined in same way as 10/1/2003 •Same as 2003

---

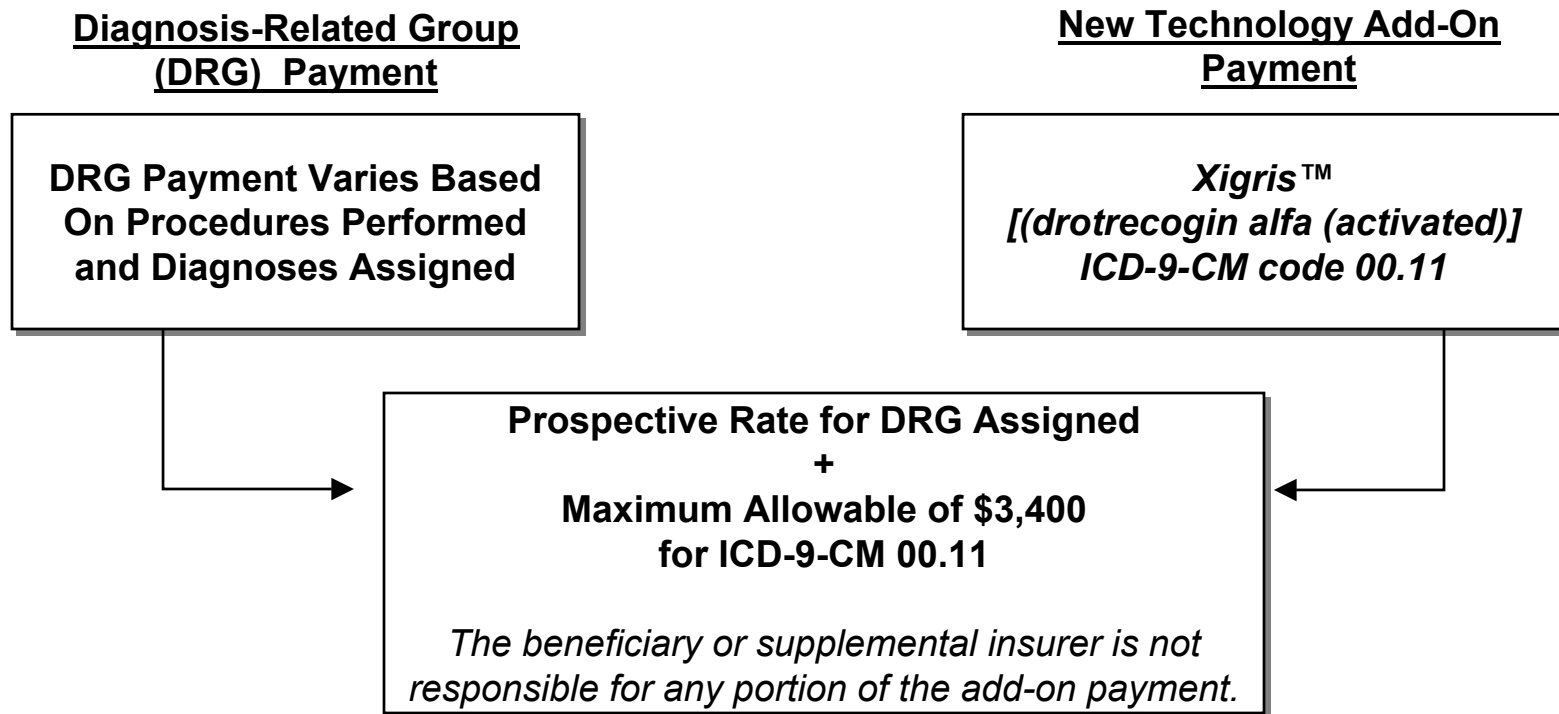
[1] The Secretary *may* disregard calculated ASP if it exceeds the WAMP (widely available market price = price a prudent physician or supplier would pay for the drug considering discounts and other concessions routinely available to a prudent physician or supplier) or Medicaid AMP (average manufacturer price) by 5% in 2005, and thereafter by a percentage threshold amount determined by the Secretary.

# Medicare Drug Reimbursement Examples

# With New Part D Coverage, Determining Medicare Payment for Drugs will Become Increasingly Complex

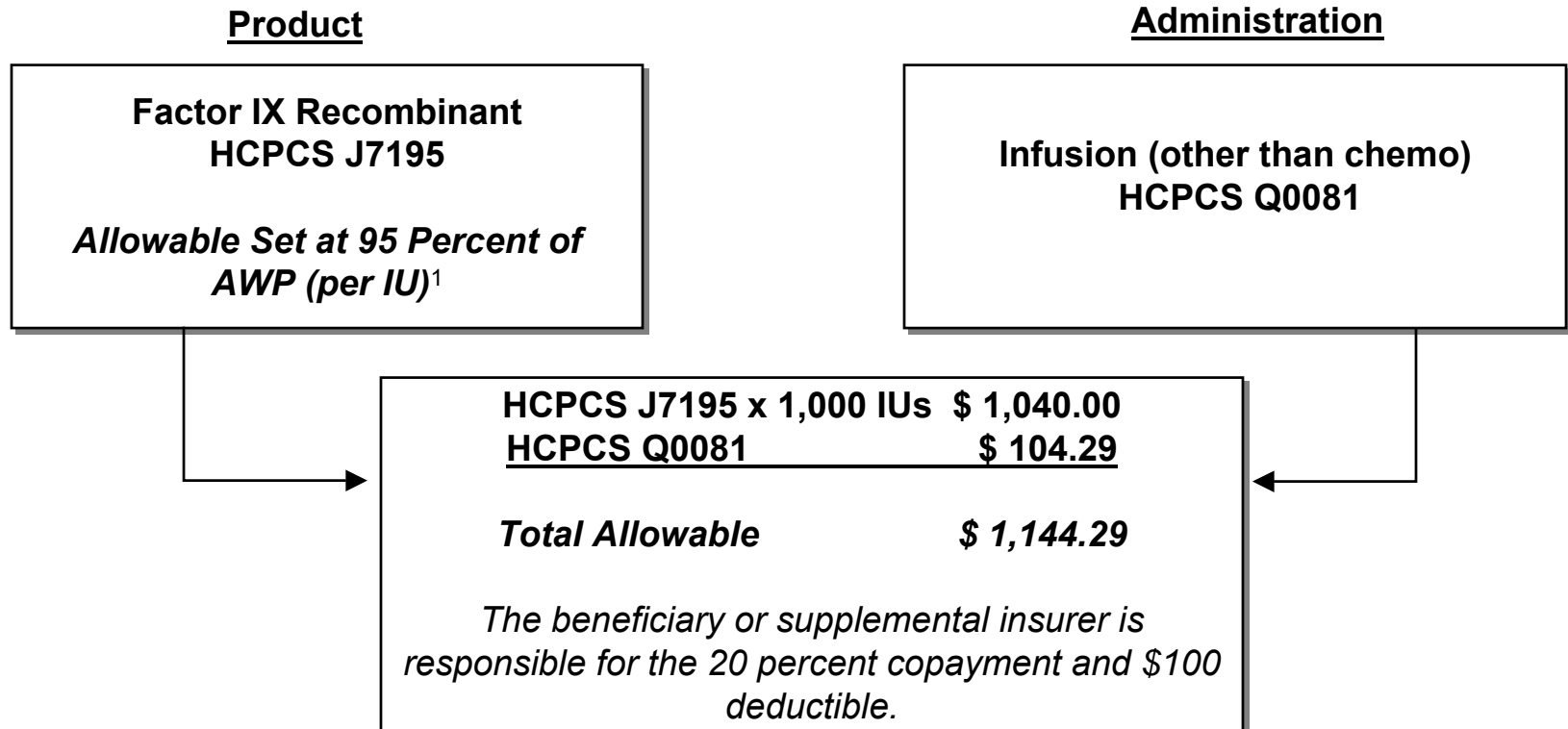
- The following examples illustrate payment differences:
  - Medicare Part A hospital inpatient new technology add-on payment,
  - Medicare Part B hospital outpatient payment for a specified covered outpatient drug,
  - Medicare Part B physician office payment for a covered new drug,
  - Medicare Part B statute-mandated home infusion coverage for immune globulin intravenous (IGIV), and
  - Medicare Part D drug retail pharmacy coverage.
- Payment rates are not uniform across these settings.

# Medicare Part A New Technology Add-On Reimbursement Example: Hospital Inpatient



- Cases qualify when the cost for the entire case exceeds the total DRG payment amount. In such cases, Medicare pays for up to 50 percent of estimated costs of the new technology. The extra payment for Xigris™ is capped at \$3,400 (half of the estimated cost of Xigris™).

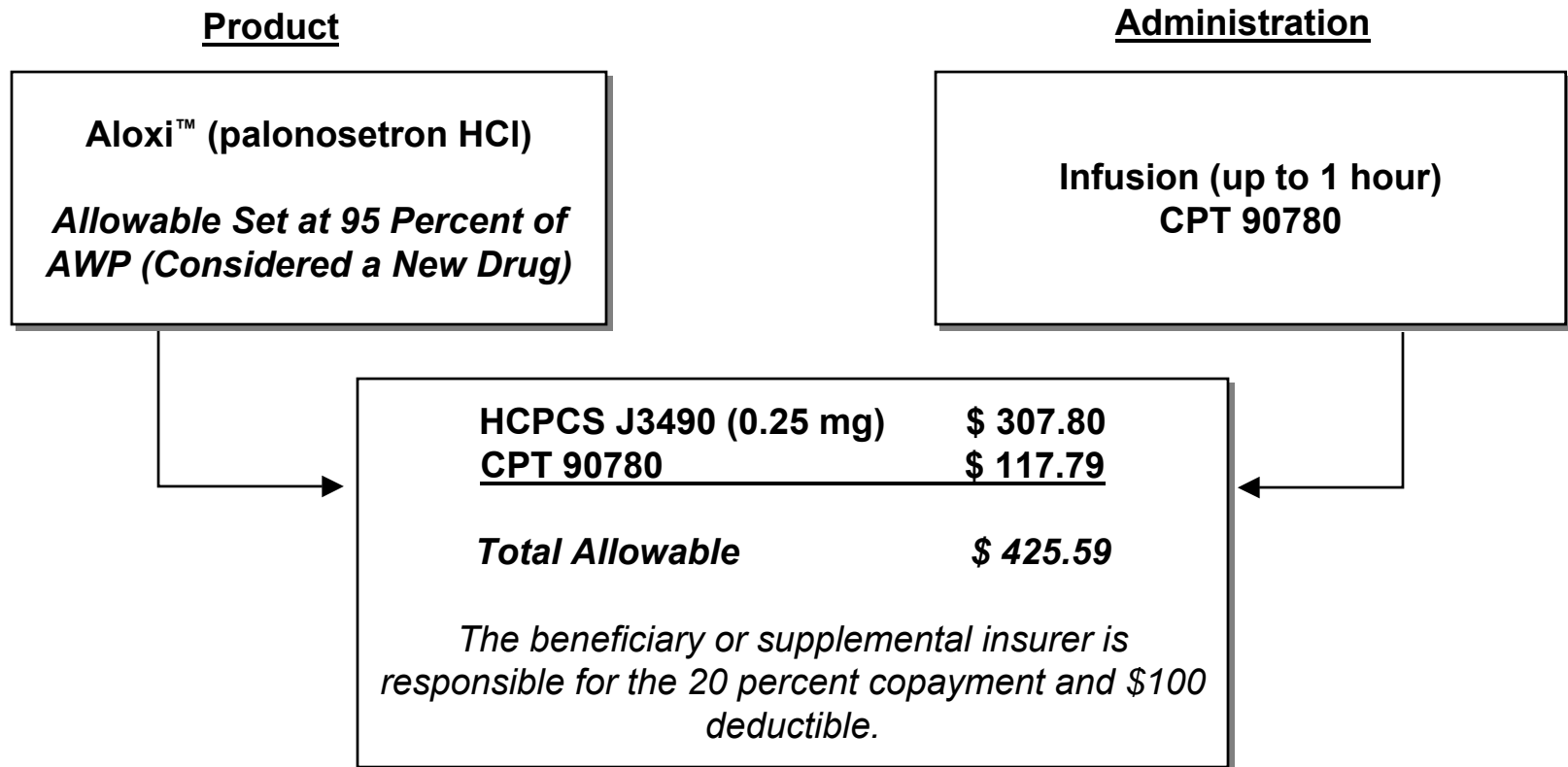
# Medicare Part B Drug Reimbursement Example: Hospital Outpatient



- Other than Xigris™, hemophilia clotting factors are the only drugs and biologicals that are separately reimbursed in the hospital inpatient setting.

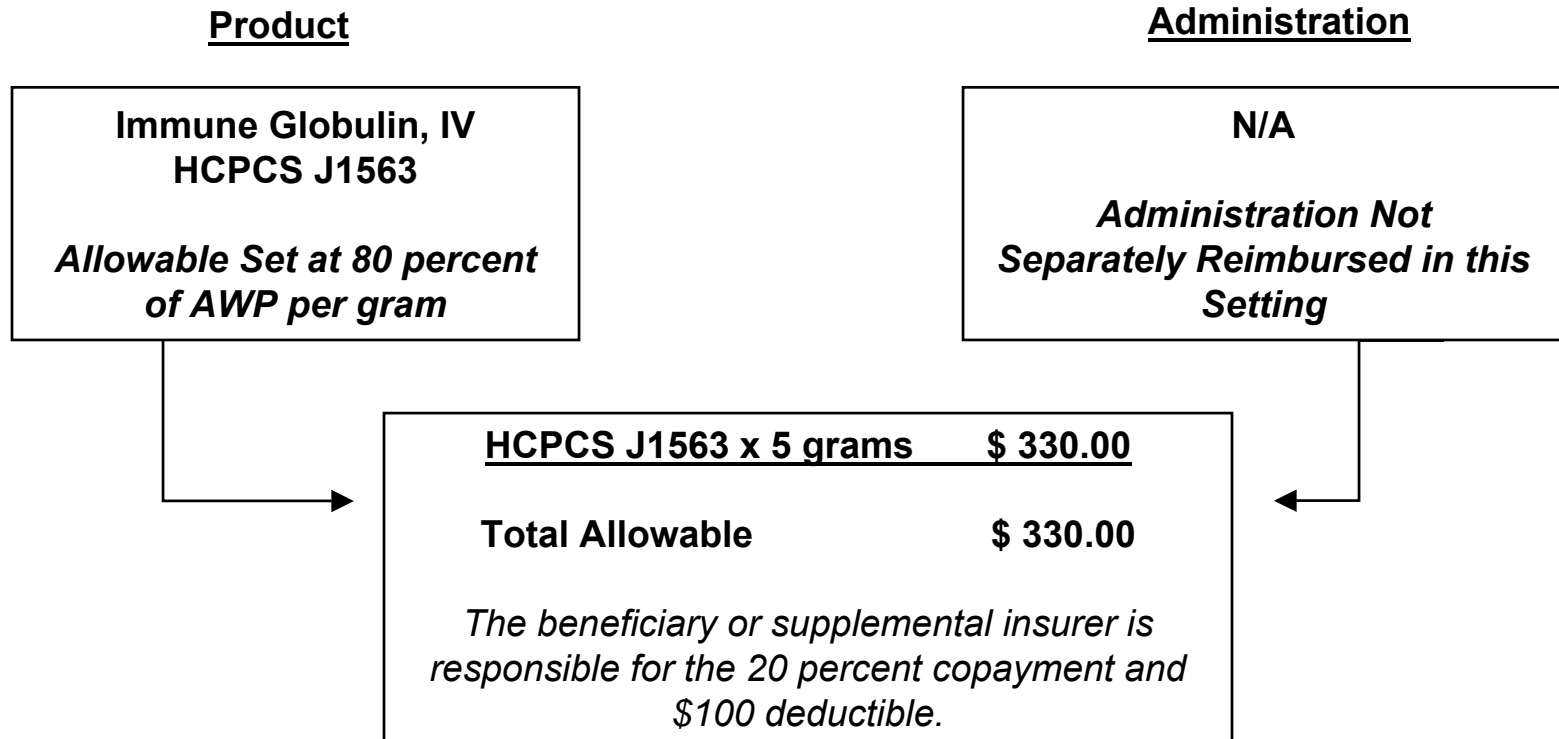
<sup>1</sup> In the inpatient setting, IUs must be rounded up to 100 and billed as 1 service unit.

# Medicare Part B Drug Reimbursement Example: Physician Office

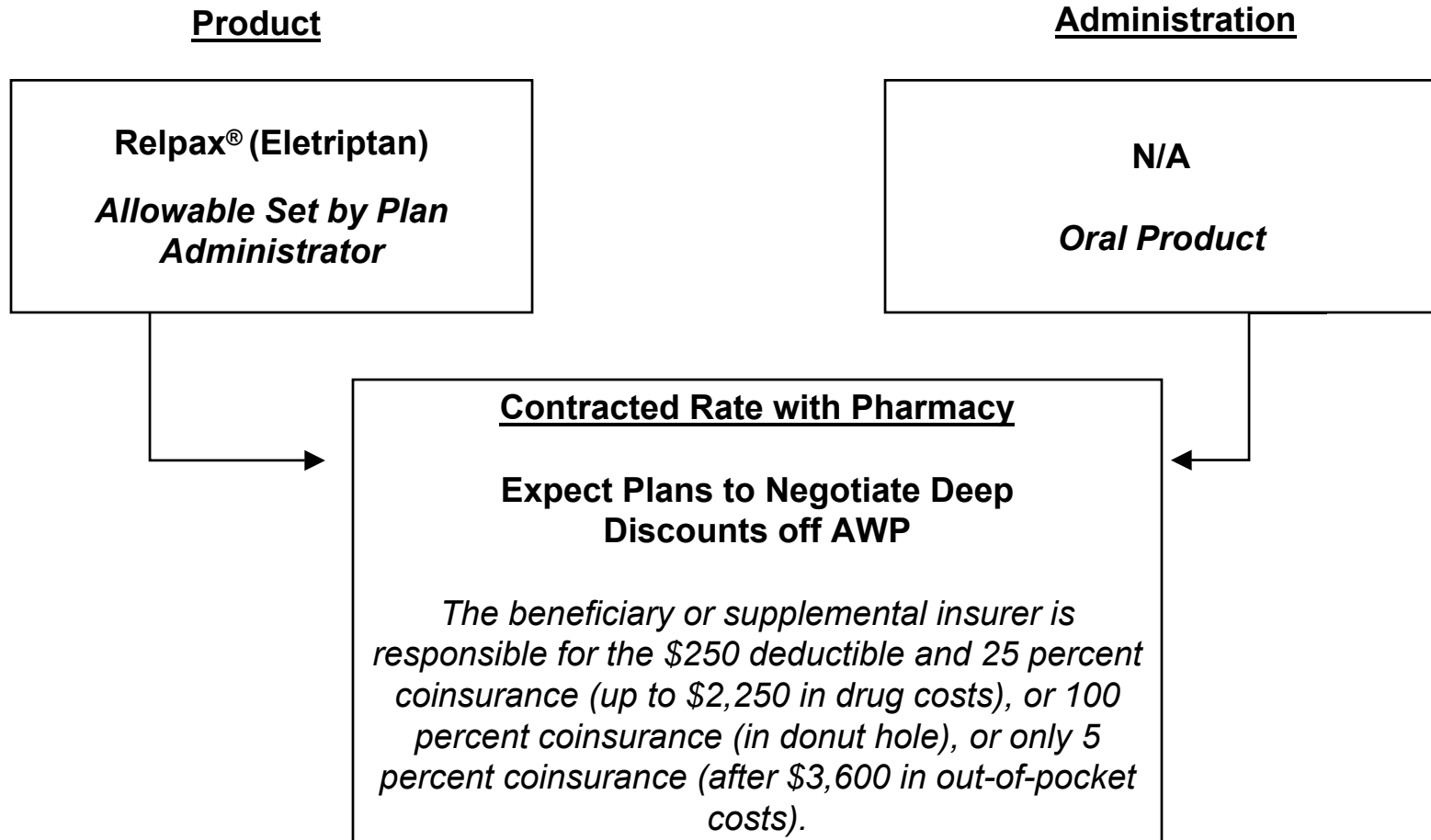


- In the physician office setting, payment for infusion services has increased by as much as 176 percent from last year's rates.

# Medicare Part B Drug Reimbursement Example: Home Infusion (Statute-Mandated Coverage)



# Medicare Part D Drug Reimbursement Example: Oral Prescription Drug



# Questions & Answers