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LIFE SCIENCES BOOTCAMP SERIES

Federal Contracting & Drug Pricing

James W. Kim, Lead Partner, MWE Public Sector

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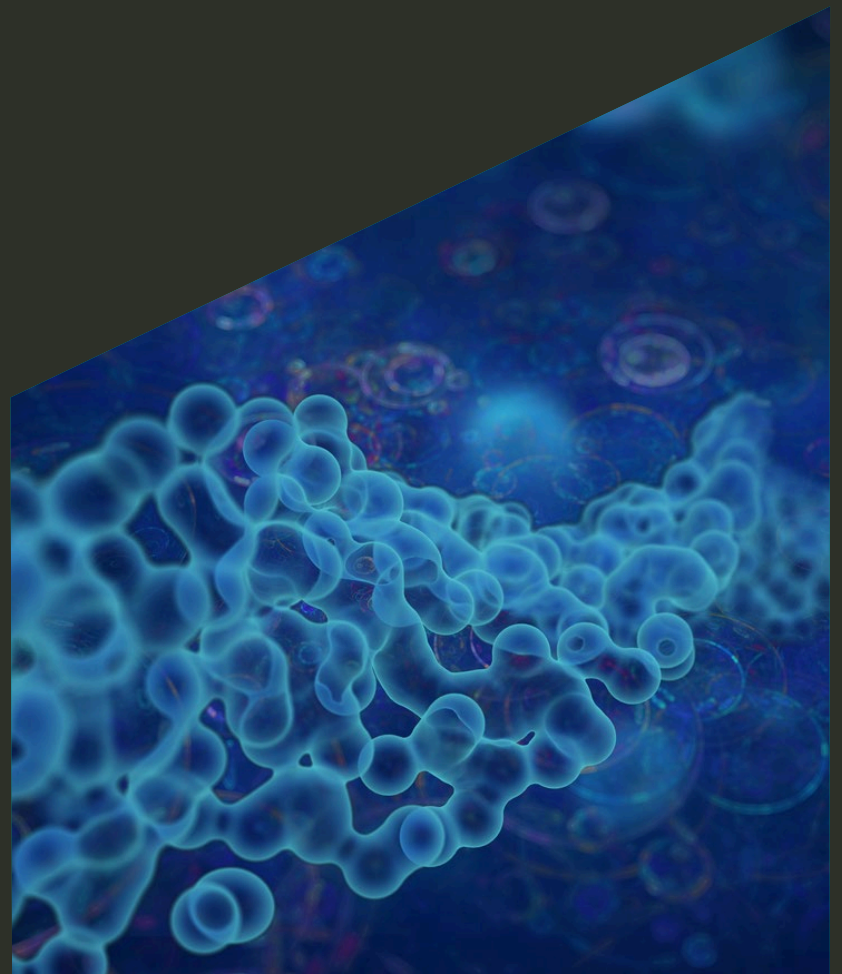

AGENDA

Government Contracts

- Process and Structure
- Federal Funding & Assistance Types
- Key Compliance Obligations

Federal Drug Pricing

- What is a Covered Outpatient Drug?
- Key Government Agreements for a COD Manufacturer
- Medicare, Medicaid & 340B

Conclusion and Questions

AN INTRODUCTION TO GOVERNMENT CONTRACTS

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GOVERNMENT CONTRACTING PROCESS AND STRUCTURE

Why do business with the Government?

The United States Government spends more than $500B in annual procurement

Recent Federal Legislation has expanded greatly the realm of Government funding programs, including CARES, EAA and ARP

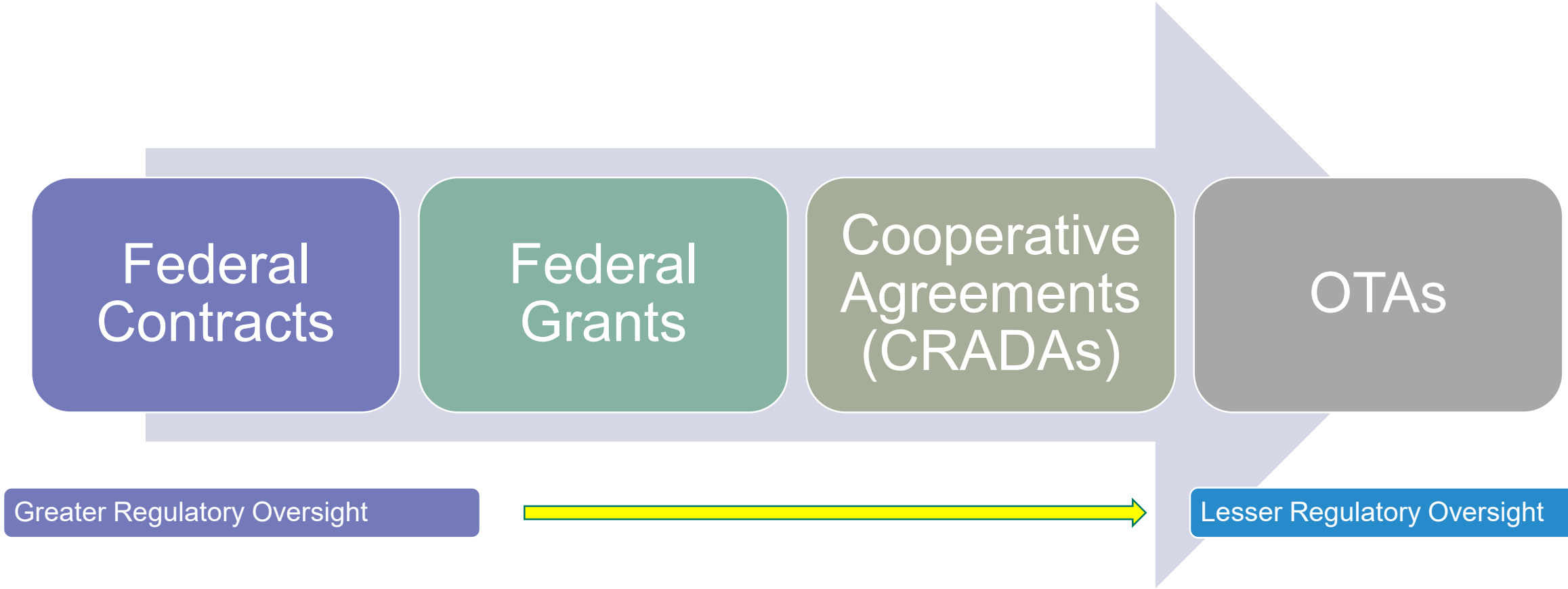
Pending expansion in Public Health/Preparedness and Domestic Medical Supply is expected to further supplement Government funded awards

How are funds Awarded?

Government awards are generally funded through annual Appropriations to the Federal Agencies

Federal Agencies Award Contracts, Grants, CRADAs, OTAs and other forms of Federal Financial Assistance

GOVERNMENT CONTRACTING PROCESS AND STRUCTURE



1. FEDERAL CONTRACTS

A Prime Contract is awarded by a Federal Agency based on appropriated funds to a Commercial Entity

- Prime Awards
- Basic ordering agreements
- Indefinite Delivery/Indefinite Quantity
- Blanket Purchase Agreements
- Multiple Award Schedule Contracts
- Letter contracts
- Purchase/Task Orders
- Distribution and Pricing Agreement (DAPA)
- Sole Source Awards

Subject to statutory requirements, FAR/DFARS and other Agency supplemental regulations, Executive Orders and regulatory guidance

2. FEDERAL GRANTS

Grants are used to Fund non-Government entities and individuals	Subject to Statutes, Regulations (Uniform Guidance (Title 2 of the CFR)), Executive Orders and official guidance
• Used to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and • Not to acquire property or services for the Federal awarding agency or pass-through entity's direct benefit or use	• FFATA Reporting • Single Audit Requirement • Allowability & Allocability

3. COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRADA)

CRADA Defined:

- A CRADA is an agreement between one or more Federal laboratories and one or more non-Federal parties
- The Government provides its laboratories and may provide personnel, services, facilities, equipment, intellectual property, or other resources but **no funds to non-Federal parties (e.g. private companies)**
- Non-Federal parties may provide funds, personnel, services, facilities, equipment, intellectual property, or other resources
- Purpose is the conduct of specified research or development efforts which are consistent with the missions of the laboratory

When to use a CRADA:

- Private company contributes funding to research or requests IP rights
- Research project involves collaboration between government and private sector researchers
- Personnel, services, facilities, or equipment are to be supplied by the government, private company, or both

4. OTHER TRANSACTION AUTHORITY

OTA is the term commonly used to refer to the authority of the DoD to carry out certain prototypes, research, and production projects.

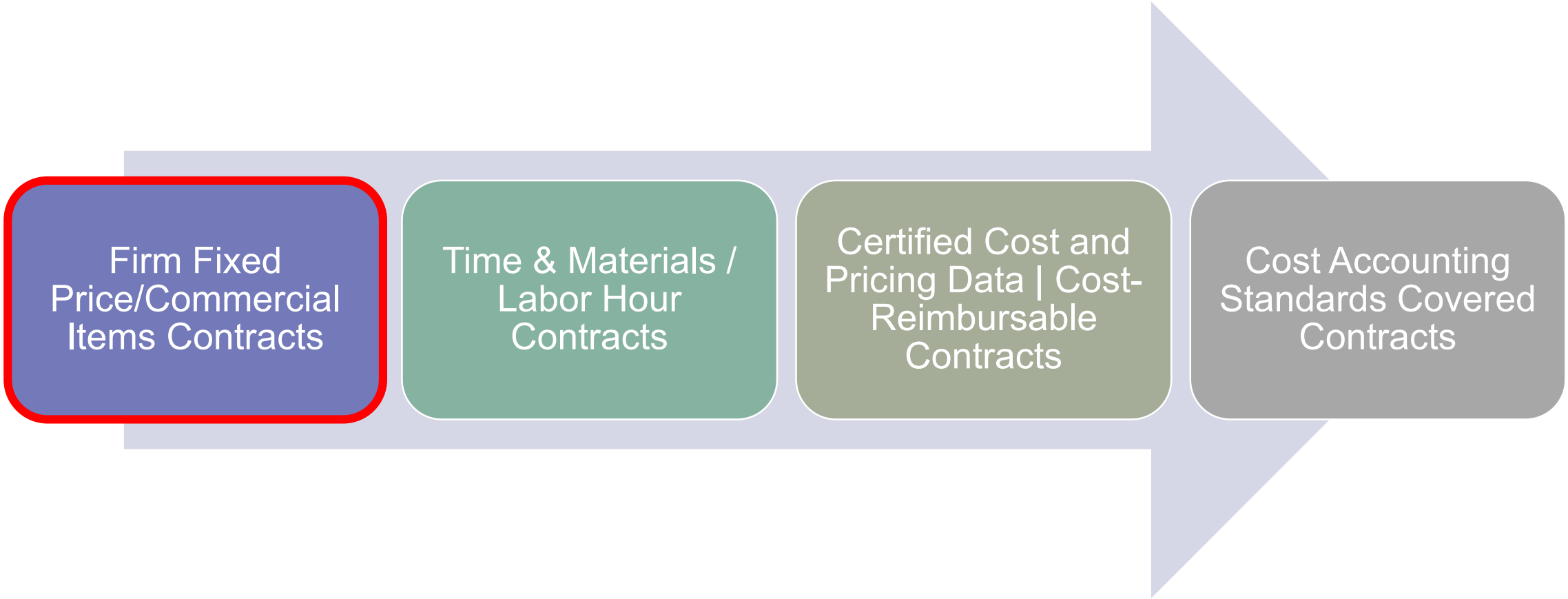
Other Transaction authorities were created to give DoD the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments (*See* 10 U.S.C. 2371b)

The DoD has permanent authority to award OT for (1) Research, (2) Prototype, and (3) Production Purposes.

5. OTHER FEDERAL FINANCIAL ASSISTANCE EXAMPLES

- Provider Relief Fund
- Paycheck Protection Program
- Government Loans (Main Street Loan Program / SBA)
- Direct Appropriations
- Interest Subsidies

PAYMENT/COST STRUCTURE OPTIONS



KEY COMPLIANCE REQUIREMENTS

FAR CLAUSES FOR GOVERNMENT CONTRACTS

Key sources of regulatory requirements for Commercial Item Contracts

- 52.212-4 Contract Terms and Conditions-Commercial Items.
- 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items.

Note: Certain FAR clauses, *per their language*, are required to be "flowed down" to subcontractors

COMPLIANCE REQUIREMENTS FOR GOVERNMENT CONTRACTS

- Applicability of Novation Agreements (FAR 42.1204)
- Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (FAR 52.204-25)
- Contractor Code of Business Ethics and Conduct (FAR 52.204-25)
- Small Business Subcontracting Plan (FAR 52.219-9)
- Equal Opportunity (E.O.11246) (FAR 52.222-26)
- Trade Agreements (FAR 52.225-5)
- Termination for Convenience (FAR 52.249-2)
- Recordkeeping Requirements (FAR 4.7, False Claims Act, Contract Disputes Act)

ADDITIONAL COMPLIANCE REQUIREMENTS FOR VA FSS CONTRACTORS

Price Reduction Clause

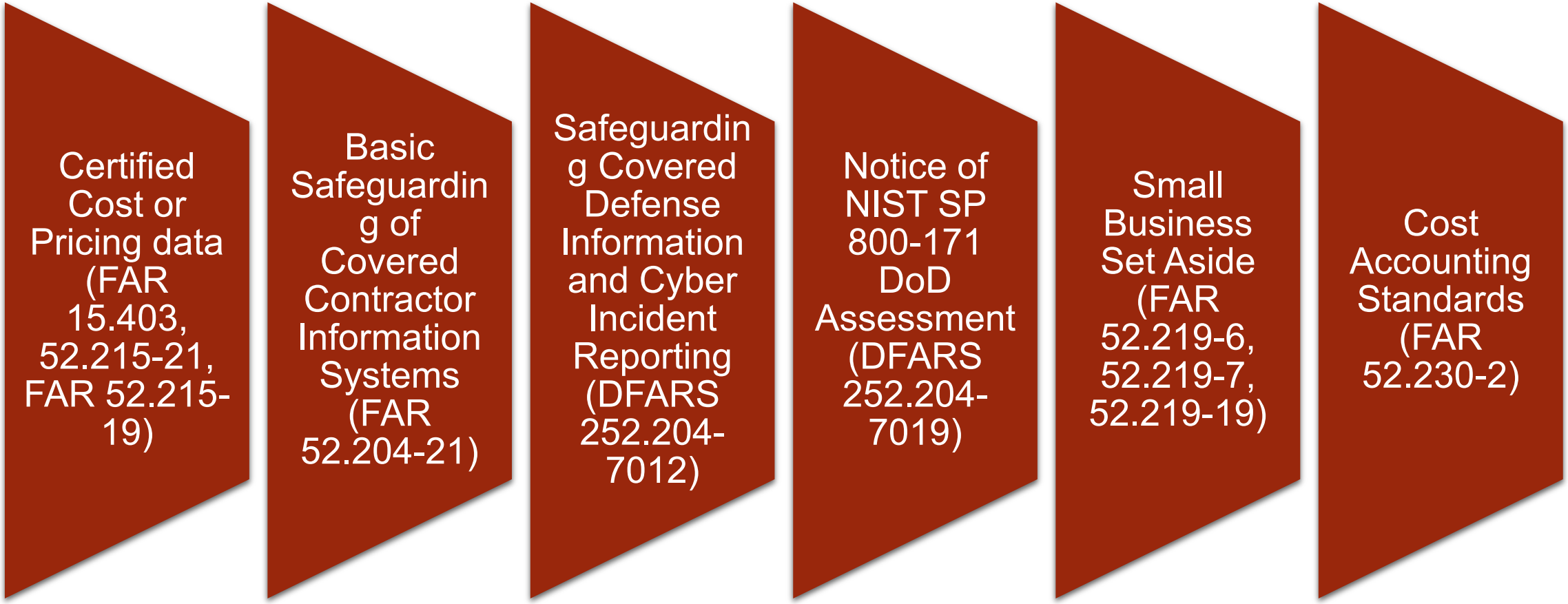
Industrial Funding Fee

Mass Modifications

Trade Agreements Act *

Distribution and Availability

CERTAIN PROVISIONS CAN TRIGGER ADDITIONAL COMPLIANCE



TOP 5 TIPS ON DOING BUSINESS WITH THE GOVERNMENT

1. Focus on the Mission
2. Doing business with the USG is bound by statute and regulation. These requirements cannot be negotiated generally, but can be addressed structurally
3. Understanding your statutory, regulatory and performance obligations are paramount
4. Be proactive regarding risk assessment and mitigation related to audit risk, compliance risk and liability exposure
5. Know your customer and engage thoughtfully – relationships are critical

FEDERAL DRUG PRICING

WHAT IS A COVERED OUTPATIENT DRUG (COD)?

- Under Section 1927(k) of the Social Security Act a “covered outpatient drug” is defined, in part, as
  - a drug which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food Drug and Cosmetic Act or which is approved under section 505(j) of such Act

WHAT IS NOT A COD?

Not "Covered Outpatient"

- Any drug, biological product, or insulin provided as part of or incident to and in the same setting as certain services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug)

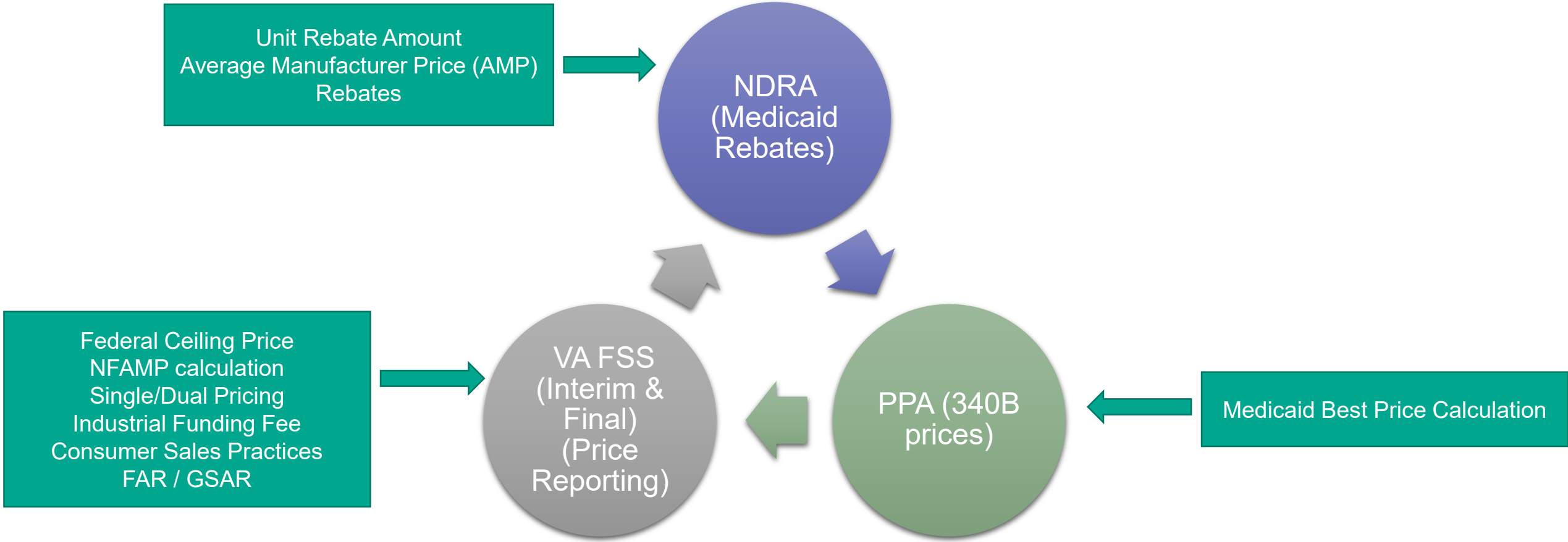
Not a "Covered Drug"

- Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA
- Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in the COD definition
- Any drug product or biological used for a medical indication which is not a medically accepted indication; or
- Over-the-counter products that are not drugs

WHAT AGREEMENTS ARE APPLICABLE TO A COD?

- National Medicaid Drug Rebate Agreement (NDRA)
- Pharmaceutical Pricing Agreement (PPA)
- Federal Supply Schedule (FSS) Agreement

COVERED OUTPATIENT DRUG: KEY FEDERAL AGREEMENTS



NATIONAL MEDICAID DRUG REBATE AGREEMENT (NDRA)

If a manufacturer's drug is a COD, the drug is covered by Medicaid if the manufacturer participates in the Medicaid Drug Rebate Program ("MDRP") by entering into a NDRA

Under the MDRP, the manufacturer agrees to provide Rebates to the state Medicaid agency for CODs

Medicaid Rebates are calculated based on formula. *See* 42 U.S. Code § 1396r–8(c).

KEY MANUFACTURER'S RESPONSIBILITIES UNDER NDRA

- Calculate and report all required pricing data on every COD by NDC
- Calculate a URA and make a rebate payment in in accordance with each calculated URA to each State Medicaid Agency
- Report all CODs and corresponding drug product, pricing, and related data to HHS upon entering into the NDRA and update as necessary
- Report quarterly pricing data to HHS for all CODs
- Report information including monthly AMPs and monthly AMP units for all CODs
- Make rebate payments no later than 30 days after receiving the state rebate invoice
- Make rebate payments on all of its CODs for as long as the agreement is in force and state utilization data reports that payment was made for that drug, regardless of whether the manufacturer continues to market the drug.
- Keep records of data and other material from which the AMP calculations and best price were derived and make such records available to HHS upon request.

PHARMACEUTICAL PRICING AGREEMENT (PPA)

A PPA must be signed by a manufacturer as a condition of participating in the Medicaid program

Section 340B requires a manufacturer that sells a COD to eligible entities to sign a PPA with the Secretary of Health and Human Services (HHS) in which the manufacturer agrees to charge a price for CODs that will not exceed the AMP decreased by a rebate percentage

OTHER MANUFACTURER'S RESPONSIBILITIES UNDER PPA

Submit to HHS a list of the CODs, the AMP, baseline AMP, and the best price of such CODs

Retain all records related to the above for at least 3 years from the date of creation

Afford HHS reasonable access to records relevant to the manufacturer's compliance with the terms of the PPA

Permit CMS to share AMP and unit rebate amount submitted under the MDRP

Participate in the HRSA Prime Vendor Program *

VA FEDERAL SUPPLY SCHEDULE (FSS) CONTRACT

A manufacturer of CODs must offer those drugs to FSS in order to receive FHCP reimbursement (including Medicare/Medicaid), regardless of whether the drugs are purchased through the FSS

Prices on the FSS contract are determined based on the interplay of statutory requirements and terms of the FSS contract (including incorporated regulations)

VA FEDERAL SUPPLY SCHEDULE (FSS) CONTRACT

Drug manufacturers must make CODs available for sale on an FSS contract at statutorily-capped pricing, known as the Federal Ceiling Price (FCP), to “Big Four” agencies (VA, DoD, Public Health Service (PHS) (including Indian Health Services) and the United States Coast Guard)

Other Government Agencies (OGAs) and other eligible FSS purchasers are not entitled to FCP, so VA allows manufacturers to decide whether to extend FCPs to OGAs

SINGLE VS DUAL PRICING

Single Pricers

- Maintain single price list
- Voluntarily provide FCP (or lower) pricing to all FSS-eligible purchasers as the FSS “contract price”

Dual Pricers

- Establish two prices: (1) Big Four price capped at FCP and (2) OGA negotiated price that serves as the FSS contract price

MEDICARE, MEDICAID AND 340B

MEDICARE DRUG COVERAGE, REIMBURSEMENT AND PAYMENT

Medicare Part A

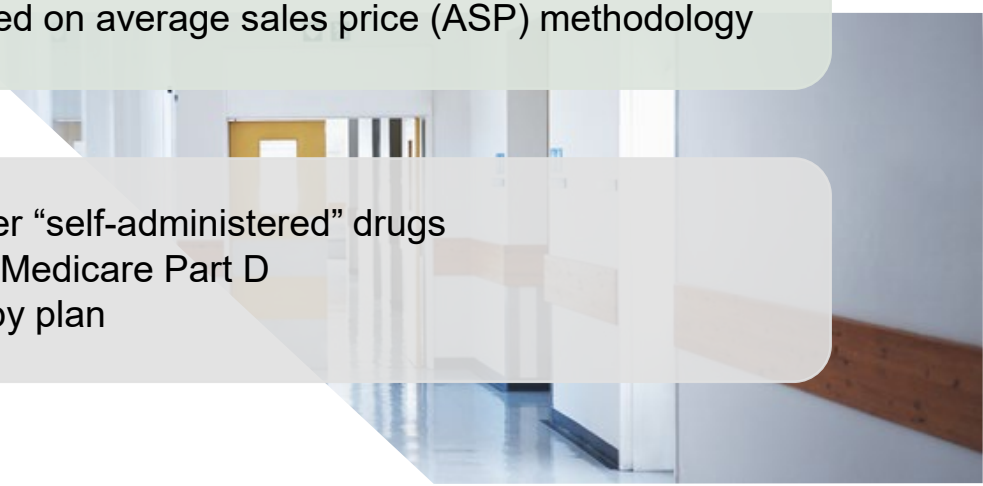
- Pays for institutional care using prospective payment systems (PPS)
- Under PPS, Medicare makes a single payment to the facility for all care related to the encounter
- Drugs are not typically separately paid, with some limited exceptions

Medicare Part B

- Pays on a “fee for service” basis for drugs administered by a physician in their office and for some drugs administered in a hospital outpatient department or clinic
- Separate payment is generally based on average sales price (ASP) methodology

Medicare Part D

- Medicare Parts A and B do not cover “self-administered” drugs
- Coverage is only available through Medicare Part D
- Payment rates and coverage vary by plan



MEDICAID DRUG PAYMENT

Medicaid Drug Rebate Program (MDRP)

- Manufacturers must enter into rebate agreements with HHS in order for their drugs to be covered by Medicaid

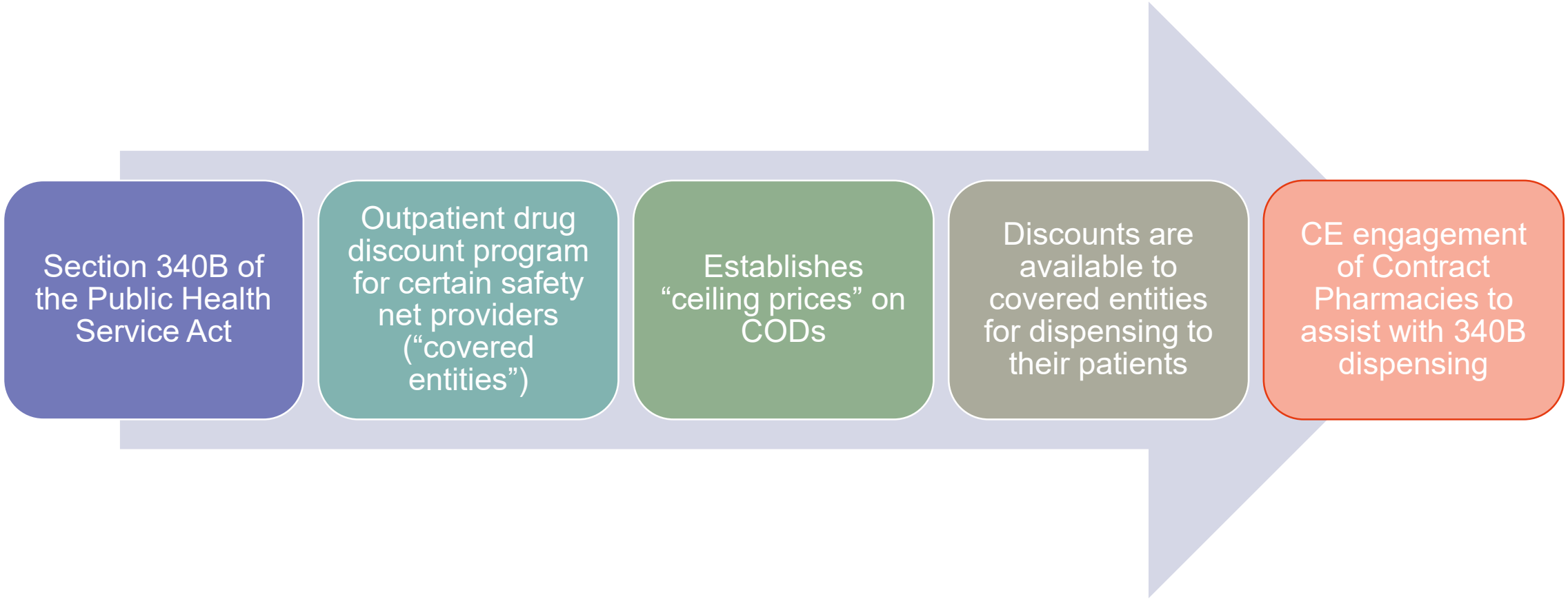
Federal Pricing

- Federal Upper Limits (FUL) cap ingredient reimbursement for certain generic drugs based on Average Manufacturer Prices (AMP)
- Payment limit for all drugs to ensure that Medicaid does not pay more than the price generally available to the public

State Pricing

- Considerable variability in drug pricing between states
- Overall, states typically pay the lowest of:
  - Acquisition Cost plus dispensing fee
  - Federal Upper Limit plus dispensing fee
  - State Maximum Allowable Cost plus dispensing fee
  - Usual and customary charges
- Medicaid managed care organizations (MCOs) are not bound by rules regarding ingredient costs like drugs purchased through Medicaid fee-for-service

340B PROGRAM



Q&A | CONCLUSION

James W. Kim, Lead Partner, MWE Public Sector

JaKim@mwe.com

202-756-8386