

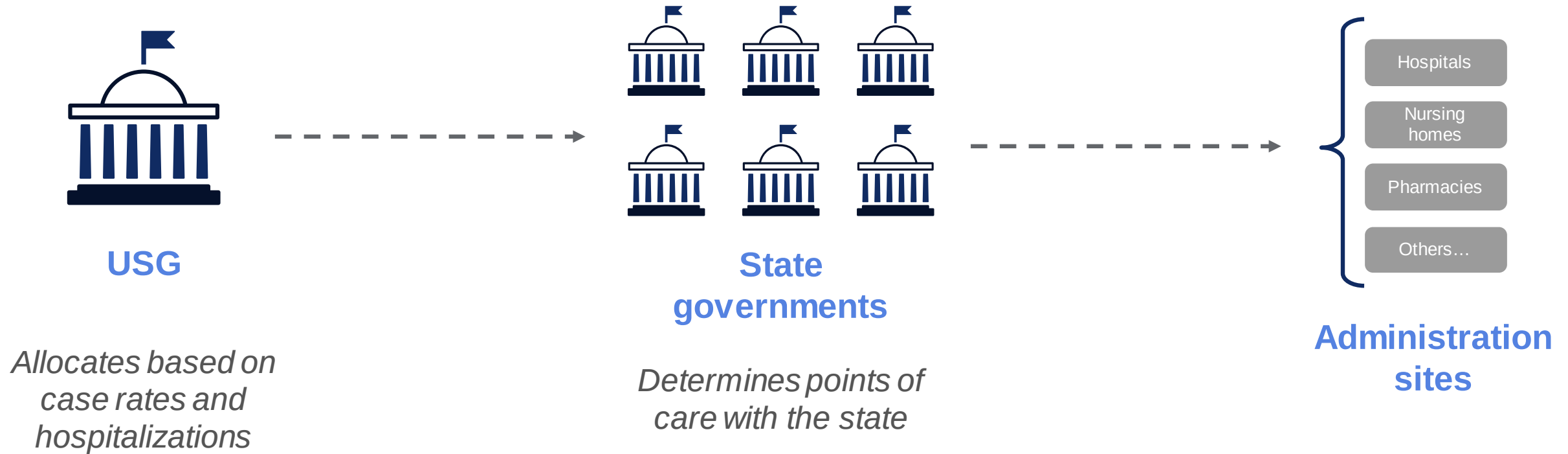


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Monoclonal Antibody Allocation Considerations at the Federal Level

**John T. Redd, MD, MPH, FACP
ASPR Chief Medical Officer**

Monoclonal antibody allocation process



Principles for Federal allocation when resources scarce

- 1 Maximize use of existing infrastructure within USG, manufacturer and distributor channels
- 2 USG to allocate to state governments when product is scarce
 - Allocations aim ensure both *geographic* and *temporal* equity
- 3 States responsible for allocation to final points of care
- 4 Manufacturer tracks pharmacovigilance and follows mandatory reporting guidance

Two data sources from HHSProtect will inform mAb allocations

1

Confirmed Hospitalizations (7- Day Incident)

- Entered daily via TeleTracking at hospitals: “How many confirmed COVID-19 cases admitted in last 24h period?”
- Data has a known lag, as it typically takes 1-2 weeks for hospitalization of patients
- Complete and timely (98% of facilities report at least once weekly; 89% report daily)

2

Confirmed Cases (7- Day Incident)

- All confirmed cases
- Contributes overall magnitude of case load
- Captures emerging cases in near real time

Allocations to be weighted combination of case count on hospitalizations and confirmed cases

Inpatient infused therapeutic

1.0/0.0 (Hospitalizations/confirmed case count)

Example:

- State A has 1,000 hospitalizations; 10,000 confirmed cases
- Weighted case count: $(1,000 \times 1.0) + (0.1 \times 0) = 1,000$
- Allocation based on hospitalization data

Used for remdesivir during federal allocation (May 2020 – September 2020)

Outpatient infused therapeutic

1.0/0.1 (Hospitalizations, confirmed case count)

Example:

- State A has 1,000 hospitalizations; 10,000 confirmed cases
- Weighted case count: $(1,000 \times 1.0) + (0.1 \times 10,000) = 2,000$
- Allocation based on weighted case count

Currently used to allocate mAbs

Takeaways

- USG has allocated over **337K+ patient courses of monoclonal antibodies** to states, territories and federal entities
- Federal allocation methodology is **designed to divide resources among states, who then have flexibility** to determine allocation within their individual jurisdiction
- States can employ a **variety of models to allocate within their jurisdiction to achieve equity goals**, and do not need to follow the federal model
 - Some employ similar logic as used at the federal level; others use capacity or bed space as a proxy (among others)



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Thank you!