

# Immunotherapy Delivery: Workflow and Work Process Considerations

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# OVERVIEW AGENDA

- Overview of Maryland's regulatory environment
- Building blocks of a successful program
- Building a separate I-O clinic
- Where we are
- Next steps

# Building Blocks of Successful I-O program



- Multidisciplinary care/shared decision-making
- Expertise in administration/evaluation and recognition of immune related side effects
- Patient education and support
- Clinical trials
- Administrators who understand and support the development of program

# MARYLAND: A Cautionary Tale

- In 2014 Maryland received approval for a demonstration waiver from CMMI (Centers for Medicare and Medicaid Innovation Center) to operate a unique hospital reimbursement model.
- Waiver required Maryland to cap annual hospital revenue growth to 3.58% while achieving \$330 million in Medicare savings over a 5-year period.
- In response to this new waiver agreement, Maryland's Health Care Cost Review Commission created a fixed revenue model for each Maryland hospital called the GBR - Global Budget Revenue which establishes a prospective revenue base which is based on 2013 hospital volumes.

# Incentives: Fee-for-Service vs. GBR

## Fee-for-Service Model

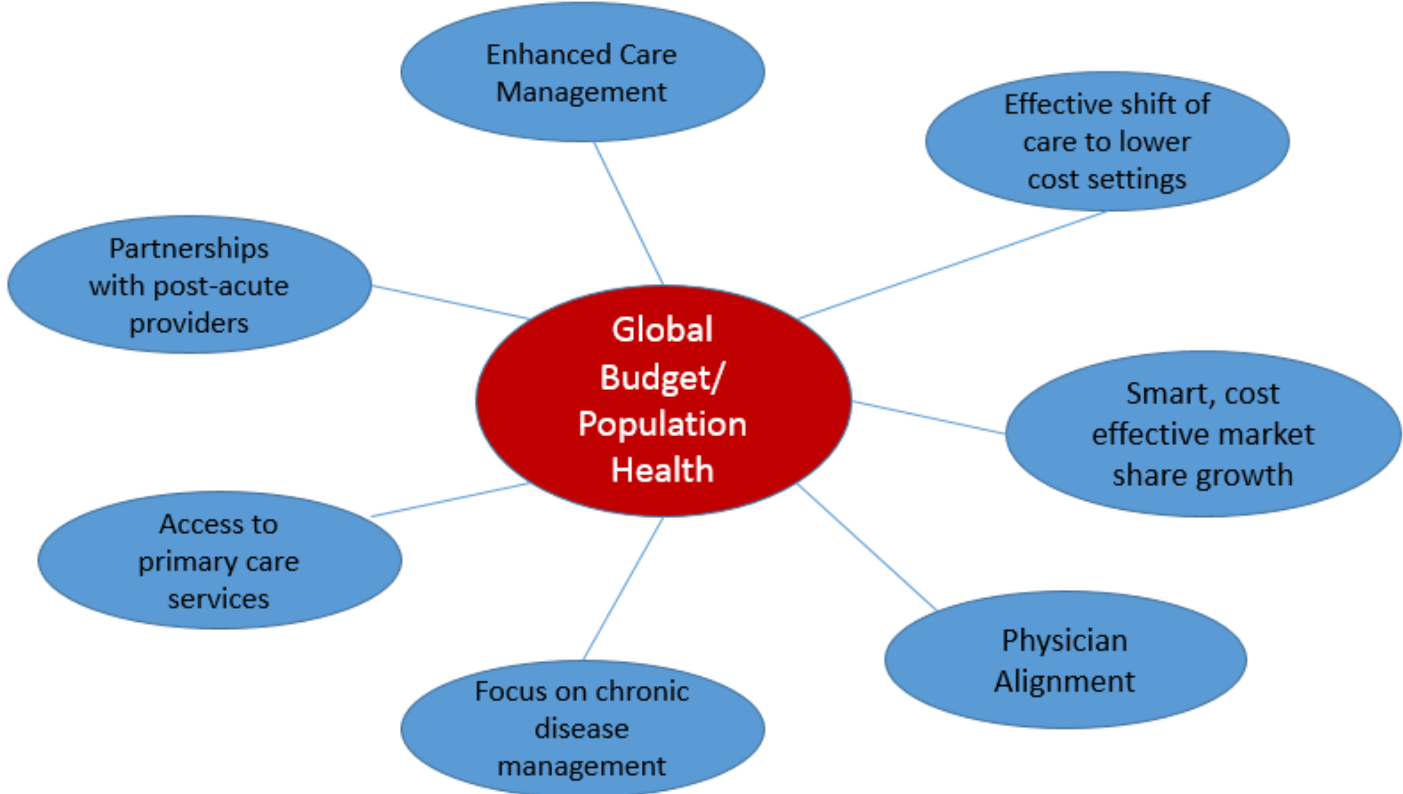
- Volume growth
- Case-mix growth
- Inpatient per case utilization
- Hospital setting preferred over lower level setting
- Inpatient status preferred over outpatient status
- Emergency department throughput
- Bed turnover

VS.

## Global Budget Revenue Model (GBR)

- Reduce avoidable volumes with effective case management and quality improvement.
- Thoughtful controlled shift to lower cost settings.
- Focus on chronic disease management
- Partnerships with sub-acute and long-term care facilities
- Physician alignment
- Investment in Health Information Exchange

# Global Budget/Population Health Initiatives



# Maryland Waiver Performance Dashboard

## Cumulative Performance – Jan 2014 to Most Recent Data Available

		Maryland Performance	Cumulative Target	
<b>ALL-PAYER HOSPITAL SPENDING GROWTH PER CAPITA</b> <small>(compared to base year Maryland - CY 2013)</small>		<b>4.14%</b> spending growth	<b>11.13%</b> spending growth or below	PERIOD Jan '14 - Dec '16 vs. 2016 ceiling  DATA HSCRC monthly financial data
<b>MEDICARE HOSPITAL SPENDING GROWTH PER BENEFICIARY</b> <small>(compared to national)</small>		<b>\$533</b> million in savings	<b>\$132</b> cumulative savings at year 3	PERIOD Jan '14 - Nov '16 vs. 2016 target  DATA CMS data*
<b>MEDICARE ALL PROVIDER SPENDING GROWTH PER BENEFICIARY<sup>1</sup></b> <small>(compared to national)</small>		<b>-1.18%</b> spending difference <small>(MD growth rate was -0.16%)</small>	no more than <b>0%</b> above national growth rate <small>(national growth rate was 1.02%)</small>	PERIOD Jan '16 - Nov '16 vs. CY 2016 target  DATA CMS data*
<b>MEDICARE READMISSION RATE</b> <small>(compared to national)</small>		<b>-5.96%</b> decrease	<b>-5.15%</b> decrease or more	PERIOD Jan '14 - Oct '16 vs. 2013 Base Year  DATA CMS data, V. 6*
<b>MARYLAND HOSPITAL ACQUIRED CONDITIONS RATE</b> <small>(compared to base year Maryland - CY 2013)</small>		<b>-46.45%</b> decrease	<b>-13.31%</b> decrease or more	PERIOD Jan '16 - Sep '16 vs. Jan '13 - Sep '13  DATA HSCRC data

March 2017

<sup>1</sup> All provider spending growth is limited to 1 years. In CY 2015, Maryland was higher than the nation by 0.71 percent which means we a percent above the nation in a single year, and cannot rise above the national growth rate for two consecutive re in jeopardy of failing if this continues in the third year.

<sup>2</sup> Data contain summaries provided by the federal government that have been prepared for Maryland, but are not official federal data. Data are preliminary and contain lags in claims. There may be material differences in results when final data are received.

# MARYLAND: A Cautionary Tale

- The fixed nature of revenue under the Global Budget Revenue (GBR) Model provides financial incentives for hospitals to ensure patients are provided high quality, well-coordinated care throughout the continuum of care.
- Through better coordinated care where providers are better aligned, unnecessary testing and avoidable hospital admissions can be prevented thus decreasing the total cost of care for Maryland residents.
- One flaw of the GBR model: Since the revenue cap is based on 2013 volumes, hospitals do not see increases in their revenue cap for new technology and drugs (i.e., immunotherapy). Therefore alternative settings of care must be considered for new drugs such as immunotherapy.



# Saint Agnes Hospital

- Member of the Ascension Health
- Sole Ascension in Maryland
- Loosely aligned clinical programs with University of Maryland
- 275-bed teaching hospital (IM, surgical residents, no Fellows)
- Hospital-based Cancer Institute (Regulated Space)
- 8 Medical Oncologists (5 FTE equivalents)



# I-O Dream Team

- Physician champions – development of local criteria and guidelines
- Clinical coordinators – NP /nurse navigator
- Core infusion nurses
- Financial counselor/Social work
- Oncology pharmacist



# Patient selection

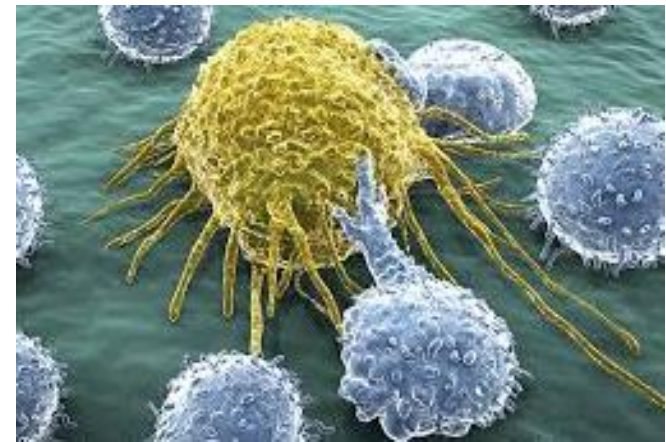
- Patients presented at tumor board if possible to assess clinical eligibility (weekly lung, GI, Heme )
- Approved indication versus Compendia/NCCN recommendations
- Screened for possible clinical trial participation
- Financial review with preauthorization (Commercial) or review against approved indication (Medicare)
- Financial counselor meets with patient, applies for appropriate patient assistance
- If not approved indication, request free drug

# Patient Education

- New patient orientation visit
- Patient/caregiver meet with Nurse Navigator/Social Work/Financial Counselor/Nutrition (One-on-One)
  - Full visit if first treatment (approximately 90 minutes)
  - Expedited if subsequent (approximately 60 minutes)
  - Provides patient education binder/I-O specific wallet card
    - Provides specific I-O toxicity guides
    - Clear guidelines of indications for telephone call
    - Reminder 24 hour/7 day access with phone numbers

# Why set up a I-O Center

- Improve patient experience
  - Developing a community of patients treated the same way
  - Developing relationships with a smaller group of providers
- Nursing expertise
  - I-O toxicities are very different from standard chemotherapy
  - Recognition better with greater experience
  - Managing toxicity
- Financial
  - Depends on regulatory landscape
  - 340B pricing ?



# Setting up I-O Center



- Issues to consider
  - Where (physical or virtual)
    - Within general infusion area
    - Separate space
  - Adjacencies
    - Pharmacy
    - Laboratory
  - Scheduling
    - With physician appointments
    - Separate day
  - Staffing
    - RN
    - MD
    - Support

# Where

- We decided separate space to define as “Specialty Clinic”
  - Financial (regulated space versus unregulated)
  - Space limitations as I-O grows
  - Decrease risk of “Drift of Specialness”
- Disadvantages
  - Needed to find new space in already crowded outpatient departments
  - Capital expense to “refit” including chairs, pumps
  - Separate registration
  - Loss of efficiencies and crosscover
  - MD required to cover, impact on seeing patients in Onc Clinic
  - RNs – must have 2 regardless of number of patients

# Adjacencies

- We initially found space in an building on campus but across a parking lot
  - Meds made in pharmacy in Cancer Center, transported by CMA to clinic
  - Area not covered by METs team/code team
  - Weather - It snows in Baltimore
  - Patient dissatisfaction with space
- Moved after 6 months to area in unregulated space within the hospital
  - Maintained drug preparation within Cancer Institute
  - Approximately 10 minute walk to area
  - Different parking lot and entrance for patients
  - Lab is within Cancer Institute area



# Schedule

- We decided to start with one day a week, Friday.
  - Started in AM only, now expanded to full day.
- Have capacity to expand as program grows.
- Patients do not see provider or get labs on same day.
  - Most of our patients live within 20 minutes of the hospital.

# Staffing Clinic

- 4 nurses have been selected to staff the clinic, rotates
- All nurses continue to work in oncology infusion area on other days
- 2 nurses staff clinic each session
- As grows, will add dedicated CMA, now “borrow” from infusion area
- Pharmacy staffed in infusion area
- Preregistration done during physician visit
- One physician scheduled to supervise clinic
- Emergency care provided by hospital Mets team

# Flow

- Patient seen by oncologist to discuss treatment
- Case presented at multidisciplinary tumor board (if appropriate)
  - Assessed for clinical trial
- Care plan for I-O is entered into Mosaiq
  - Notifies pharmacy, preauthorization
- New patient orientation visit
  - Navigator, social work, financial counselor
- Preauthorization is done/approval to begin
- Patient meets with physician within 3 days to review labs and sign consent

# Treatment Phase

- Patient is scheduled for I-O clinic
- Goes directly to I-O clinic
- RN in clinic has reviewed labs and orders before arrival
- RN reviews I-O toxicity checklist
- If no new findings, turns in order
  - We have decided that drug will not be mixed that day until patient seen and approved
  - Adds about 20 to 30 minute wait
- I-O drug administered
- Before leaving, I-O side effects reviewed, wallet card given
- Patient is called following week by RN to evaluate side effects

# Follow-Up

- Physician visit within 3 days of next dosing
  - Meets with primary nurse for toxicity evaluation
  - Labs drawn and reviewed
  - Toxicity evaluated
  - Orders approved



# Management of Toxicity

- Patients seen by MD/NP within 2 days prior to each infusion.
- Immune-mediated symptom checklist reviewed before each dose by RN. Positives reviewed with MD/NP.
- Drug specified follow-up tests included in care plans.
- ER and hospitalists educated about immune-mediated toxicities and management.
- **MOST IMPORTANT.** Continued reinforcement to patients and family about the signs and symptoms of I-O toxicity.

# Set up

- 2 treatment rooms
  - 2 chemo chairs and 2 visitor chairs in each room
- Triage room
  - RN toxicity evaluation and IV start room
  - Privacy for toxicity discussion
  - Patient can wait until chair is ready
- Physician workspace recently reappropriated
- No registration space/staff area currently (under negotiation)

# Work in progress

- Have open position for Oral/I-O nurse navigator for 8 months
  - Currently primary nurses and breast nurse navigators are doing the education
- Need to do a patient satisfaction survey
- Growing, now have had up to 9 patients a session
- Need to revise our education program
- Need to continue to outreach to hospitalists/ER for education
  - Staff turnover



# Next steps

- Participating in the Institute for Clinical Immuno-Oncology (ICLIO) Visiting Experts program to improve program.
  - Scheduled for May 19, 2017
  - Participants
    - Physicians
    - I-O nurses
    - Pharmacy
    - Social Workers
    - Financial counselor
    - AVP cancer services
    - Onc operations manager



# It Takes a Village

To safely bring this exciting new treatment options to appropriate patients.

To continue to evaluate new agents/combinations.

To figure out how to manage the escalating costs facing our patients and providers.



Thanks to my favorite villagers

# QUESTIONS

Thank you for participating in the ACCC Webinar. Presentation slides and archived recording will be available at [acc-cancer.org](http://acc-cancer.org).



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