ACE 2020 Annual Meeting

Update on Regulatory Changes

Thursday, January 23, 2020

CONFIDENTIAL

CHAMBERHILLSTRATEGIES

ECG MANAGEMENT CONSULTANTS

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Agenda

I. Background

II. Federal Health Policies

III. Other Updates

IV. Takeaways for Oncology Programs

V. Questions and Answers

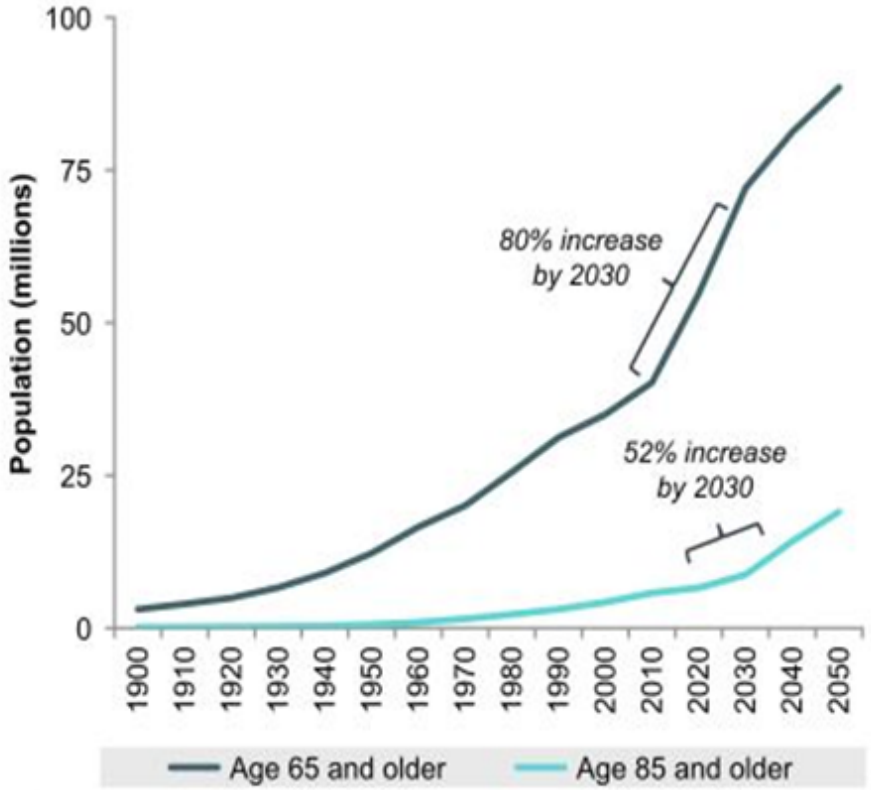
I. Background

I. Background

Medicare and Medicaid Growth

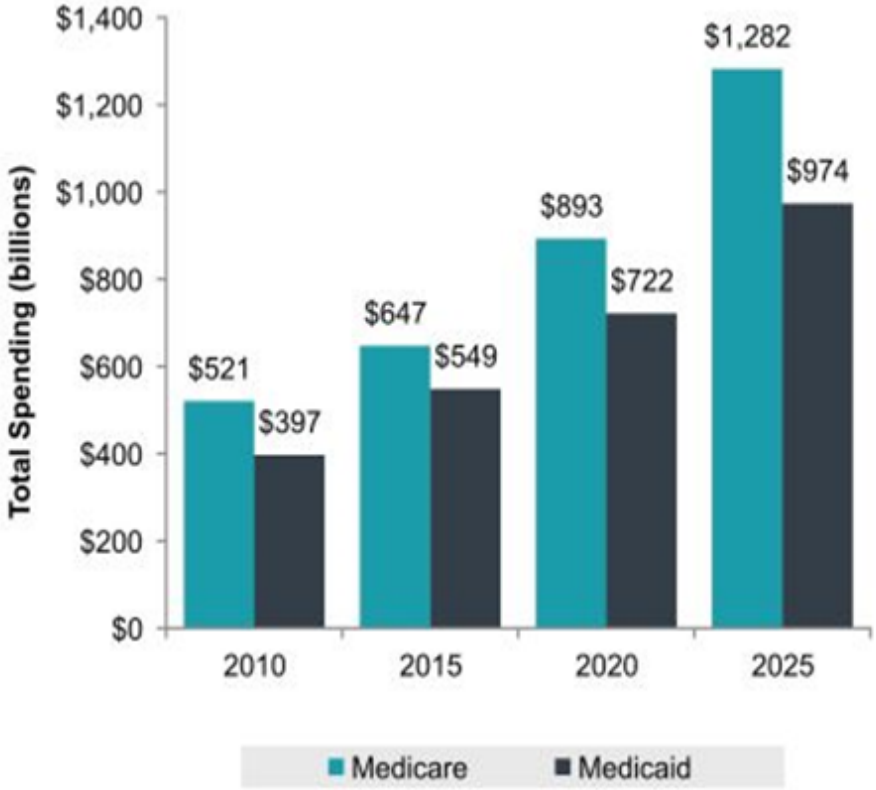
About 3.6 million people age into Medicare every year, creating a greater impetus for the government and providers to rethink how care is delivered and funded.

Population Projections



Source: US Department of Health & Human Services (HHS), Administration on Aging.

Projected Spending



Source: Centers for Medicare & Medicaid Services (CMS), National Health Expenditure Data.

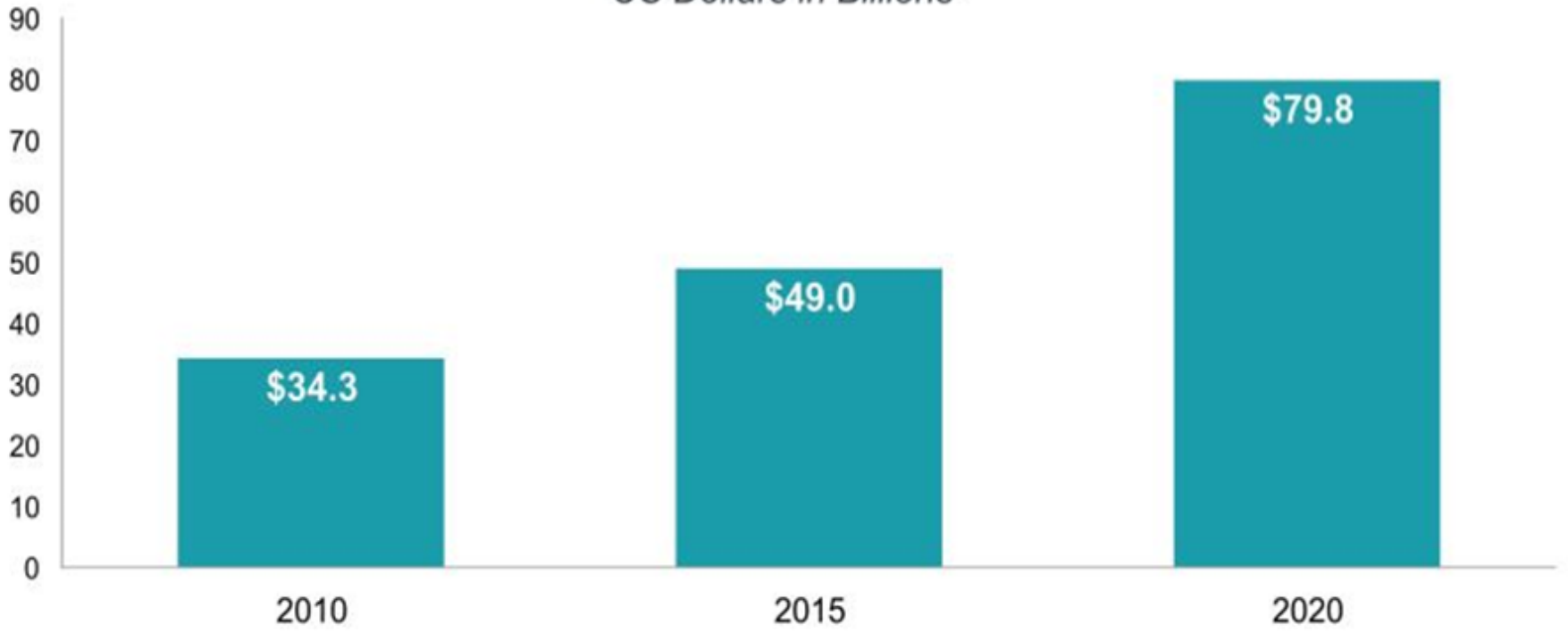
I. Background

US Spending on Oncology

US spending on oncology care is projected to grow rapidly, doubling between 2010 and 2020.

Estimated Annual US Spending on Oncology

US Dollars in Billions[1]



[1] Includes diagnosis, surgery, hospitalization, and palliative and end-of-life care. Source: "Global Oncology Trend Report: A Review of 2015 and Outlook to 2020" (IMS Institute for Healthcare Informatics, June 2016).

I. Background

Oncology as a Target

It is notoriously difficult to "bend the cost curve" for cancer due to its diversity and complexity.

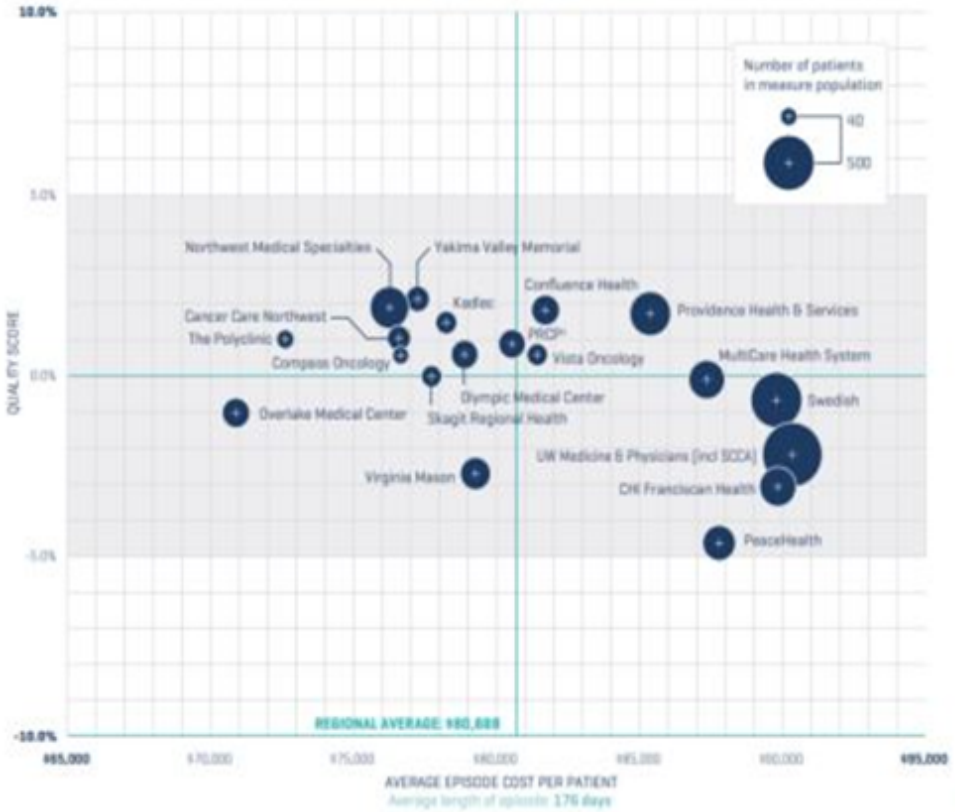
- Rapid pace of development of more precise, personalized, and novel treatments.
- Magnitude of drug development research and development costs (cancer represents 30% of pharmaceutical expenses).
- Variation in medical spend per patient.
- Lack of consistency in management of cancer care.
- Earlier diagnosis and longer life expectancies.
- Aging population.

I. Background

Oncology as a Target *(continued)*

With CMS under pressure to reduce costs, and data that demonstrates there is opportunity to lower costs without sacrificing quality, it is understandable why oncology has become a target for federal policy reform efforts.

Recommended Treatment for Breast, Colorectal and Lung Cancer Quality and Cost



Source: Fred Hutch Community Cancer Care in Washington State, Quality and Cost Report 2019.

II. Federal Health Policies

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Overview

Key Policies in Place	versus	What is On The Horizon
» CMS Site-Neutral Payment Policy » 340B Cuts Continue » Utilization Management Tools—Medicare Advantage (MA) Step Therapy and Prior Authorization » Ongoing CMMI Model Efforts		» Drug Pricing › Administration's Proposed International Pricing Index (IPI) Model › Congressional Action

II. Federal Health Policies

Site-Neutral Payment Policy

CMS is moving forward with planned rate cuts for CY 2020 despite a court ruling in September 2019 that the rate cuts were beyond the scope of powers entrusted to CMS.

- Off-campus Hospital Outpatient Departments (HOPDs) are now paid Medicare Physician Fee Schedule–equivalent rates for clinic visit services.
  - After partial implementation in CY 2019, CMS is in the process of repaying all hospitals for 2019 OPPS payments that were withheld.
  - CMS is moving forward with rate cuts for CY 2020 as previously planned.
  - CMS has appealed the September 2019 court decision.
- A lawsuit has been filed against CMS for the CY 2020 cuts.

II. Federal Health Policies

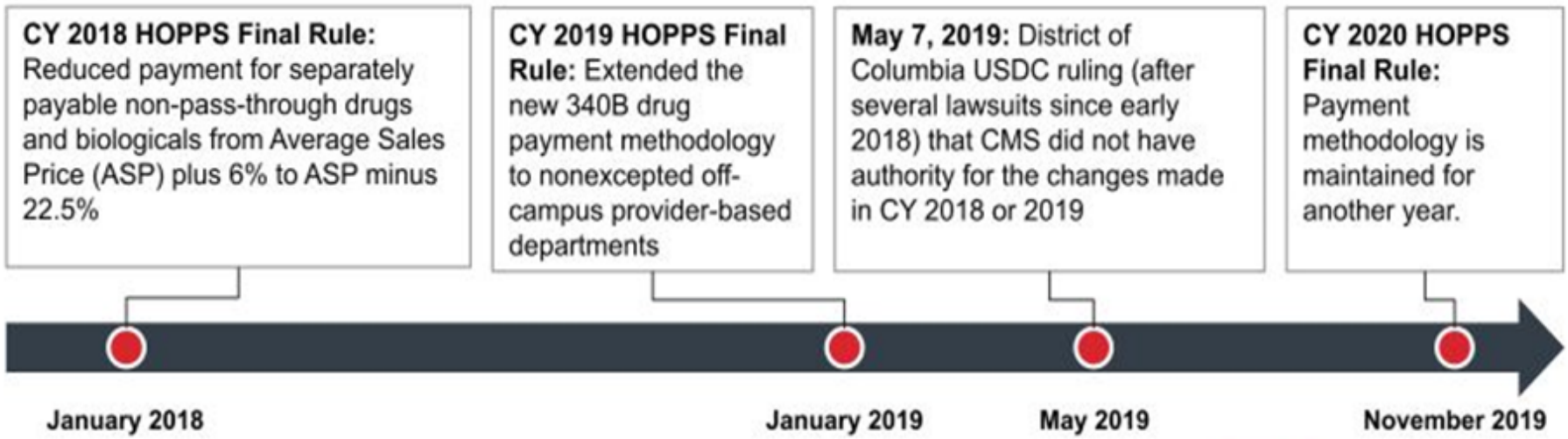
340B Program

Court rules CMS did not have authority for CY 2018-2019 cuts; CMS maintains the payment reductions for CY 2020. More to Come!

American Hospital Association™
Advancing Health in America

"A federal district court judge yesterday ruled that the Department of Health and Human Services would get **'first crack at crafting appropriate remedial measures'** to the nearly 30 percent cuts to Medicare payments affecting certain hospitals that participate in the 340B Drug Pricing Program."

Source: https://www.aha.org/news/headline/2019-05-07-judge-hhs-gets-first-crack-fixing-340b-cuts.



II. Federal Health Policies

Medicare Advantage – Utilization Management Tools

There is a focus on the use of utilization management tools to control costs in Medicare – such as step therapy and prior authorization.

Medicare Advantage (MA) plans can use step therapy for Part B drugs.

- Applies to new starts of medication; must be reviewed by the health plan's pharmacy and therapeutics committee
- Beneficiary protections

Nearly 4 out of 5 MA enrollees are in plans that require prior authorization for some services.

- Consider trajectory for MA growth among Medicare beneficiaries; more and more services subject to prior authorization

Pressure to balance need for cost containment and ensuring access to care

- Reaction of policymakers

II. Federal Health Policies

Ongoing CMMI Model Efforts – OCM/OCF

The Center for Medicare and Medicaid Innovation (CMMI) is beginning discussions on what model will replace the Oncology Care Model (OCM) when it ends in 2021.

Current Program

OCM

- Five-year model (2016–2021)
- Program Aim: Improve care coordination, access, and appropriateness while lowering total cost for Medicare beneficiaries receiving cancer treatment.

Current OCM Participating Practices

Future Program?

Oncology Care First

- Informal RFI released on November 1, 2019 *(comment period ended December 13, 2019)*
- Proposed five-year model (2021–2026)
- Intended to address major issues with OCM's methodology and design.
- Would be a multi-payer model, with commercial payers and state Medicaid agencies partnering with CMS to align their payment models with OCF.

Other proposed models such as OCM 2.0 and MASON have either been retracted or stalled.

II. Federal Health Policies

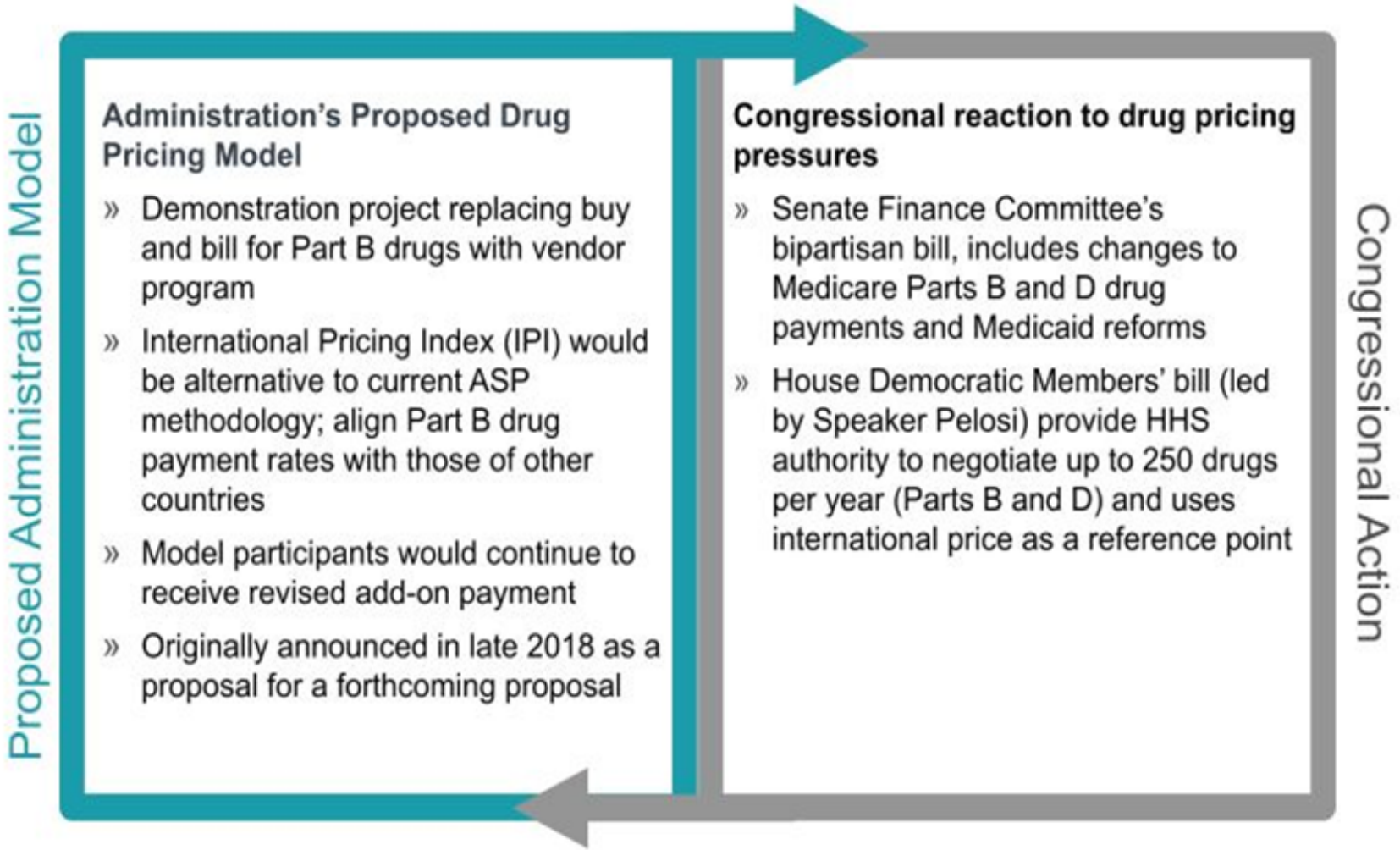
Ongoing CMMI Model Efforts - Radiation Oncology Model

CMMI proposed the Radiation Oncology (RO) Model in July 2019.

- Physician group practices, hospital outpatient departments, and freestanding radiation therapy centers for radiotherapy episodes of care
  - Model would qualify as Advanced Alternative Payment Model (APM) and Merit-based Incentive Payment System APM under the CMS Quality Payment Program
- Key elements of the five-year model:
  - Prospective, episode-based payments (split into professional and technical components) – 17 cancer types
  - Mandatory participation in selected Core Based Service Areas
  - Transitions to site-neutral payment via adjusted national base payment
  - Link payments to quality using reporting and performance on quality measure, clinical data reporting, and patient experience
- Mixed reaction among stakeholders
  - Generally applaud some aspects, good first step toward enabling RO to participate in alternative payment models
  - But, outstanding concerns with other aspects, particularly mandatory participation
- Projected to begin either 1/1/2020 or 4/1/2020; awaiting additional information

II. Federal Health Policies

On the Horizon – Drug Pricing



II. Federal Health Policies

Congressional Action on Drug Pricing

- Possible Congressional Action?
  - Legislative outlook on drug pricing clear as mud
    - Senate Republican issues with SFC bill's Part D cuts
    - House Democratic bill DOA in Senate
  - Political pressures, election year, balance of power in Washington in play
  - Landscape
    - Impeachment
    - Primaries begin
    - Health care extenders before 5/22; need for offsets?
    - FY2021 appropriations
  - Who gets the win?

"The future is uncertain but the end is always near." – Jim Morrison

Part B drug payments remain highly vulnerable. If not now, likely some time.

III. Other Updates

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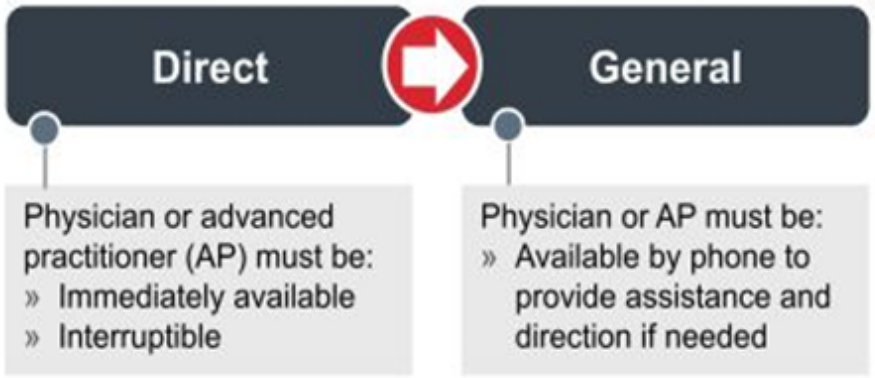
Supervision Requirements

The CY 2020 OPPS final rule has loosened the minimum required level of supervision from direct to general supervision for all outpatient therapeutic services, including chemotherapy and radiation



Supervision Requirements for Radiation and Chemotherapy

Site of Care	Required Supervision prior to CY 2020	Required Supervision for CY 2020 and subsequent years
HOPD	Direct	General
HOPD	Direct	General
CAHs and small rural hospitals	*Unenforced*	General
CAHs and small rural hospitals	*Unenforced*	General

Physician Assistant (PA) Supervision Changes

Effective January 1, 2020

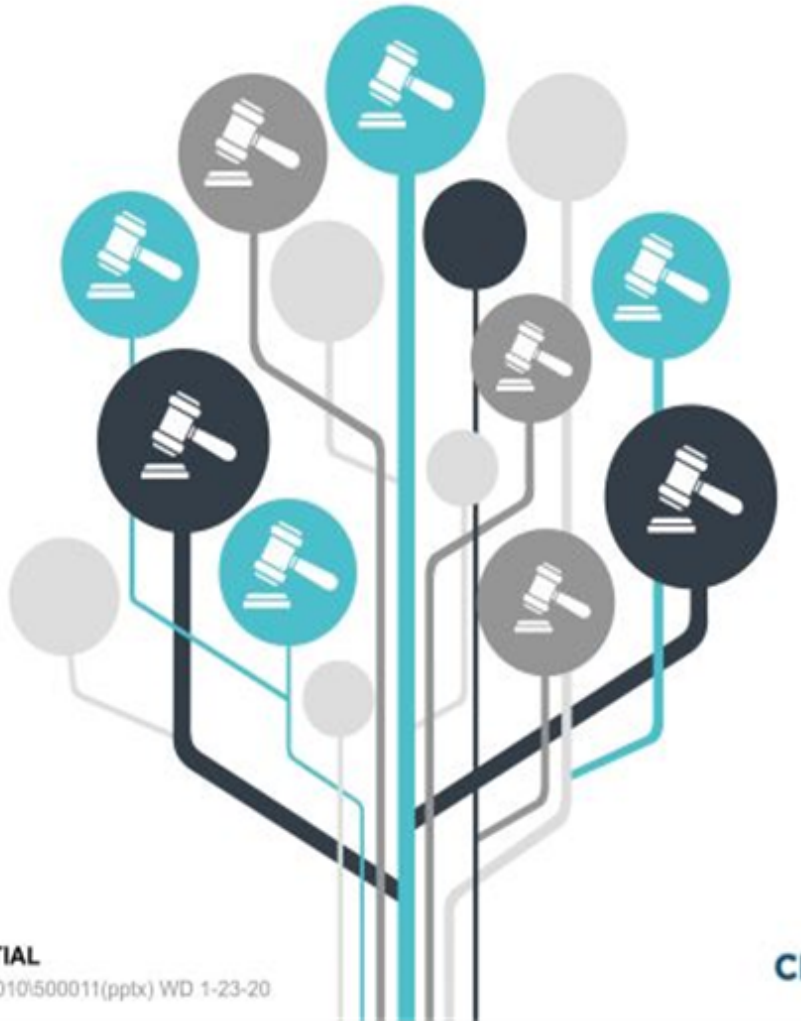
» Medicare will defer to state law to define how PAs practice with physicians.

» Reduces administrative burdens and aligns Medicare policy with the direction many states are already moving in to eliminate barriers to PA-provided care.

III. Other Updates

USP <800> Compliance

Although other USP standards were delayed in September 2019, chapter <800> went into effect on December 1, 2019.



In September 2019, US Pharmacopeia announced postponing of the official effective dates for several new and revised standards while it reviews appeals to those standards.

Chapter <800> became effective on December 1, 2019.

Although there is a temporary reprieve on other chapters (<795>, <797>, and <825>), practices should not take this as an indication that they can ease up on compliance with <800>.

III. Other Updates

Genetic Counseling Bill

HR 3235: Access to Genetic Counselor Services of 2019

- Would require that genetic counselors be reimbursed for counseling Medicare beneficiaries in the same way that these services are covered when provided by a physician.
- With the increasing numbers of genetic tests available on the market, CMS is focused on managing growing spending in this sector
- Advocates of the bill argue significant savings to CMS if certified genetic counselors help physicians and patients order the right tests.

IV. Takeaways for Oncology Programs

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Lessons for Every Practice

Payment pilots continue to generate important information regarding opportunities to reduce the cost of cancer care.

- Active case management is needed.
- Use of standardized pathways is critical to reduce variation in cost and outcomes.
- Without data and analytics, it is impossible to manage or improve performance.
- Narrow networks are essential to ensure pathway compliance and cost management.
- Leadership must look for areas of innovation to drive cost reduction across the practice.
- Provider engagement is critical; without it, change will be nearly impossible.
- Aligning a provider's compensation with the incentives in the payment model can dramatically improve engagement and compliance.
- Coding and documentation (e.g., HCCs) are critical to getting credit for the complexity of a patient population.
- Infrastructure, infrastructure, infrastructure: People, processes, technology, and so forth are vital to generating and managing the information needed to manage change.
- Patient retention is important in a risk-based environment.

IV. Takeaways for Oncology Programs

Lessons for Every Practice *(continued)*

Although the fate of today's specific payment models is unknown, oncology will remain a focus area due to the high-cost nature of the specialty, with learnings from other specialty areas (e.g., cardiology, orthopedics) likely to be incorporated into future policies and programs.

Practices should consider the following as they think about the future of oncology payment models:

- **The current system is not set up for Alternative Payment Models (APMs):** Broad adoption of APMs will be a challenge given the country's fragmented healthcare system.
- **There is no silver bullet:** There is no one perfect model, and those that succeed in the long term will have to evolve over time.
- **It will never be easy:** Any model an organization adopts will present challenges in the beginning.
- **Practices will need to focus their efforts:** Practices can realistically only participate in one APM at a time, and whatever model is selected should ideally be applied across several payers.

IV. Takeaways for Oncology Programs

Continue to Focus on Value-Based Capabilities

CMS and commercial payers will continue to hone their payment innovation strategies in coming years, and as such, oncology practices should maintain a focus on developing value-based care capabilities.

V. Questions and Answers

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