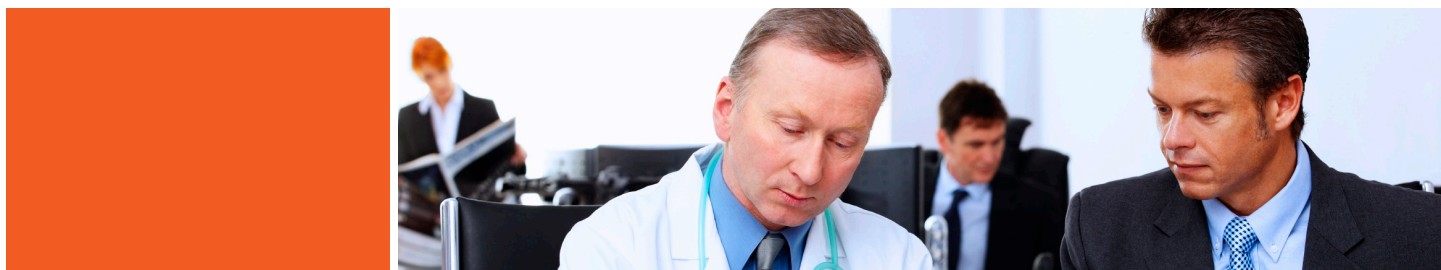


NOVARTIS OPM

NEWSLETTER

Quarterly Health Policy Updates for Novartis Oncology Practice Managers

April 30, 2010



Comprehensive Healthcare Reform Legislation is Signed Into Law

In This Issue:

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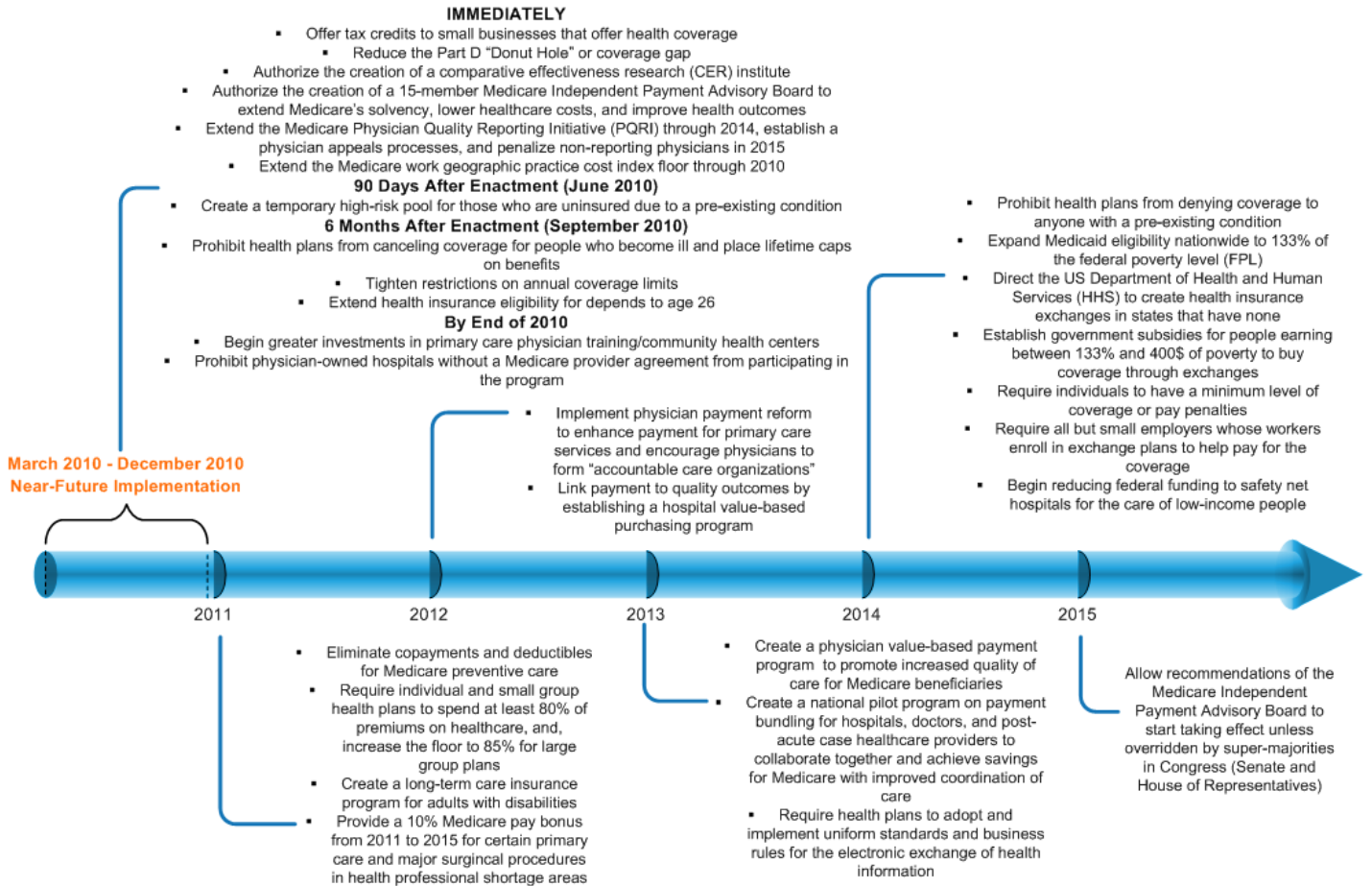
Note:

These updates are provided to you as an informational reference as a Novartis Oncology OPM speaker

On March 23, 2010, President Barack Obama signed the Patient Protection and Affordable Care Act (PPACA), and, on March 30, 2010, he signed the Health Care and Education Reconciliation Act, into law.^{1,2} Together, PPACA and the “Reconciliation Act” will eventually expand insurance coverage to 32 million Americans, while reducing federal budget deficits and implementing significant insurance market reforms.³ PPACA and the “Reconciliation Act” mark passage of the most historic and comprehensive healthcare reform legislation since the enactment of Medicare.

While comprehensive healthcare reform legislation has been signed into law, it currently does, however, lack the detail under which the provisions will be operationalized. Based on the passed legislation, the timeline for healthcare reform implementation will start as soon as immediately after enactment through 2015, as detailed below.⁴

1. <http://www.opencongress.org/bill/111-h3590/show>
2. <http://www.opencongress.org/bill/111-h4872/show>
3. http://dpc.senate.gov/dpcdoc-sen_health_care_bill.cfm
4. <http://docs.house.gov/energycommerce/TIMELINE.pdf>



With respect to the impact of comprehensive healthcare reform legislation on the oncology community, among other outcomes, it is expected to do the following:

- Keep current practice economics largely intact, as there are no specific payment cuts to providers in the law. However, providers may need to adjust to new payment models and systems that will be developed over time. Other stakeholders, such as manufacturers may be required to partially subsidize some drug expenditures.
- Keep the same major insurance players as there is no public plan option. However, providers, patients, and other stakeholders may need education about the new options.

- Eliminate the denial of coverage due to prior pre-existing conditions; as a result, more patients with cancer may have access to health insurance.
- Reduce the number of uninsured patients due to the individual mandate for healthcare insurance as well as the new options for the uninsured, such as high risk pools and increased Medicaid offerings.

The American Society of Clinical Oncology (ASCO) issued a statement regarding the passage of healthcare reform legislation, outlining its support for the following provisions:

- Guaranteed insurance coverage for patients participating in clinical trials

- Closing of the drug prescription gap under Medicare Part D
- Removal of lifetime caps on insurance coverage
- Elimination of pre-existing condition exclusions, including for children under their family policies
- Extension of health insurance eligibility for dependent children up to age 26

However, ASCO is “...deeply concerned that the legislation [PPACA] does not address the flawed Sustainable Growth Rate (SGR).”⁵ The lack of a solution to the SGR fix continues to directly impact

oncology practices that see decreased reimbursement for provider services, and, even more importantly, are not able to implement financial planning and budgeting for Medicare patients.

While it is anticipated that oncologists will not experience direct negative impact from comprehensive healthcare reform legislation, it is likely that there will be an increase in the underinsured population as well as new insurance offerings, which in turn may bring new administrative challenges for oncology practices.

President Obama Signs Memorandum to Expand RAC and Intensify Recovery Authority

On March 10, 2010, President Barack Obama signed a memorandum extending the “Payment Recapture Audits” currently implemented by the Recovery Audit Contractors (RACs) to federal agencies and executive departments. As defined in the memorandum, a Payment Recapture Audit, “...is a process of identifying improper payments paid to contractors or other entities whereby highly skilled accounting specialists and fraud examiners use state-of-the-art tools and technology to examine payment records and uncover such problems as duplicate payments, payments for services not rendered, overpayments, and fictitious payments.”⁶

Expanding the Payment Recapture Audits to a government-wide level is

intended to save \$2 billion in taxpayer money over the next three years.⁷ President Obama’s speech on this memorandum came at the same week that a physician advisory panel from the Centers for Medicare and Medicaid Services (CMS) expressed concern that physicians have been unfairly targeted under the Medicare RAC program.⁸

While physician groups have long criticized the RAC program, the White House has cited its success—including the recovery of \$900 million in taxpayer money over three years. In his speech, President Obama said, “Today, to further intensify efforts to reclaim improper payments, my Administration is expanding the use of ‘Payment Recapture Audits,’ which

5. <http://www.asco.org/ASCOv2/Press+Center/Latest+News+Releases/ASCO+News/ASCO+Statement+on+the+Passage+of+the+Patient+Protection+and+Affordable+Health+Care+Act>

6. <http://edocket.access.gpo.gov/2010/pdf/2010-5685.pdf>

7. http://image.exct.net/lib/ff0010707d6605/d/1/he2010_0220%20RAC%20WH%20memo.pdf

8. Inside Health Policy. “Obama issues memo expanding RAC recovery authority government wide” March 10, 2010

have proven to be effective mechanisms for detecting and recapturing payment errors.”⁶ Although this memorandum is not exclusive to federal agencies and executive departments that administer healthcare programs, President Obama did reiterate its main points of fraud, waste, and abuse in a separate speech specific to the healthcare sector later on that same day.

In addition to the RAC program, fraud, waste, and abuse specific to physicians is also addressed by the interagency task force, the Healthcare Fraud Prevention and Enforcement Action Team (HEAT) which was created in 2009. Historically, fraudulent activity has been uncovered most often in durable medical equipment (DME), home health, and HIV infusion claims.⁸

According to the memorandum, within 90 days of its issuance, the Director of the Office of Management and Budget (OMB) has been instructed to develop guidance on actions that federal agencies and executive departments must implement, as directed by the memorandum.⁶

For oncology practices, it is important to be aware and monitor RAC review procedures, program parameters, and state-specific timelines, while also proactively preparing internal processes to support the audits.

To access the memorandum on “Finding and Recapturing Improper Payments”, please use the following link: <http://edocket.access.gpo.gov/2010/pdf/2010-5685.pdf>

CMS Releases Second Quarter 2010 ASP Payment Rates

On March 19, 2010, CMS released the second quarter 2010 Average Sales Price (ASP) -based payment rates for physician-administered drugs. These rates reflect the actual Medicare allowables utilized to pay for most Part B covered drugs administered in the physician-office setting for the second quarter of 2010 (effective April 1, 2010 through June 30, 2010).⁹ To access the ASP drug pricing file from the CMS website, please use the following link: http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a19_2010aspfiles.s.asp#TopOfPage

Medicare allowables for most Part B drugs used in the physician office setting are based on 106 percent of the ASP,

which CMS calculates from the sales data submitted by drug manufacturers. Each quarter, manufacturers provide updated sales data to CMS, which then results in quarter-to-quarter changes in drug pricing. In this latest release, the payment allowance limits for most products are based on fourth quarter 2009 ASP data submitted by manufacturers.

In its second quarter 2010 ASP release, CMS stated that average drug prices between first and second quarter 2010 generally remained stable in the market. In addition, CMS explained that “on average, prices for the top part B drugs increased by 0.7%. For most of the higher volume drugs (35 out of the

9. http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a19_2010aspfiles.s.asp#TopOfPage

top 50), the prices changed 2 percent or less.”¹¹ Similar to recent ASP releases, CMS explained that for the top products that saw a decrease in pricing, “there are a number of competitive market factors at work – multiple manufacturers, alternative therapies, new products, recent generic entrants, or market shifts to lower priced products.” CMS will continue to monitor trends in pricing as reflected by the published ASP payment rates and product utilization within the Medicare community to ensure continued beneficiary access to Part B covered drugs.⁹

To demonstrate the variances between first quarter 2010 and second quarter 2010 drug payment, Xcenda analyzed the change in ASP for the ten oncology-related drugs and biologicals with the highest expenditures, as published by Medicare in 2008.¹⁰ In Table 1 below, the drugs and biologicals and the change in payment from first quarter 2010 and second quarter 2010 are listed.

Table 1. Medicare ASP Drug Payment for Select Products, Q1 2010 vs. Q2 2010⁹

HCPSC Code	Description	Q1 2010 ASP	Q2 2010 ASP	Percent Change Q1 vs. Q2
J9310	Rituximab injection, 100 MG	\$563.759	\$ 578.402	2.59%
J9035	Bevacizumab injection, 10 MG	\$57.456	\$ 57.569	0.01%
J2505	Injection, pegfilgrastim, 6MG	\$2,364.701	\$ 2432.499	2.86%
J9263	Oxaliplatin, 0.5 MG	\$7.616	\$ 6.825	-10.38%
J3487	Zoledronic acid, 1 MG	\$219.394	\$ 221.127	0.78%
J9201	Gemcitabine hcl injection, 200 MG	\$144.933	\$145.100	0.11%
J9355	Trastuzumab injection, 10 MG	\$64.778	\$66.416	2.52%
J9055	Cetuximab injection, 10 MG	\$49.731	\$49.732	0.002%
J9305	Pemetrexed injection, 10 MG	\$50.585	\$50.626	0.08%
J9217	Leuprolide acetate suspension, 7.5 MG	\$206.520	\$220.407	6.72%

As outlined in Table 1, among the drugs and biologicals analyzed, overall, most experienced very slight changes in payment rates of approximately over two percent or less, from first quarter 2010 to second quarter 2010.

Because variability in drug payments can provide challenges for oncology practices, it is important to monitor them carefully, and update systems appropriately.

10. <http://www.cms.hhs.gov/MedicareFeeForSvcPartsAB/Downloads/Level2CHARG08.pdf>

11. <http://www.communityoncology.org/wp-content/uploads/Avalere-COA-Oral-Oncolytics-Study-Summary-Report.pdf>

Report Released Addressing Barriers to Access for Oral Oncolytics

In February 2010, the Community Oncology Alliance (COA) in collaboration with Avalere Health released the report, “Oral Oncolytics—Addressing the Barriers to Access and Identifying Areas for Engagement,” which was a research effort to assess the access barriers to oral oncolytics.¹¹

Specifically, according to the report, “The overall objective of this engagement was to examine access challenges related to oral oncolytics and assess ways to potentially mitigate these challenges to ensure that physicians can prescribe the most clinically appropriate oncolytic for a patient, regardless of drug formulation, which is in the best interest of all stakeholders.”¹¹

Research for this project was conducted through a literature review, an analysis of public and private payer policies and claims activity, as well as stakeholder interviews. From the findings of this research, the study team outlined the current best practices which oncology offices and payers use to facilitate access to oral oncolytic medication.¹¹

Based on the findings of this report, one of the main barriers contributing to access challenges is the existing infrastructure of insurance benefit design which separates medical and pharmacy benefits, or what the authors term “the bifurcated insurance landscape.” In particular, as the medical benefit generally covers physician-administered drugs and the pharmacy benefit generally covers self-administered drugs, “artificial incentives and disincentives to use certain products” are created. In addition, the disparate patient cost-

sharing this separation causes can lead to access challenges to oral oncolytics medications. For example, if a patient has coverage only through the medical benefit, then therapies covered by the prescription drug benefit may not be considered as viable treatments, thus restricting the therapy options for the patient. Other challenges related to oral oncolytics, which were identified in this report include compliance, clinical, administrative, and clinical issues.¹¹

After reviewing the identified access challenges, the research team determined four existing best practices (intended for oncology offices and payers) that would help to alleviate some of the current issues patients face:¹¹

- Utilization of in-office pharmacy
- Inclusion of an oncology specialist on the Pharmacy and Therapeutics (P&T) of health insurance plans, either by participation of Medical Directors with an oncology specialty, or by consultation with a practicing oncologist
- Inclusion of a dedicated financial counselor as a key component to the oncology care team to coordinate a patient’s finances related to therapy
- Usage of health information technology (HIT) and electronic medical record (EMR)

In addition, the report outlines several potential areas of engagement across multiple stakeholders that should be considered when addressing access challenges to oral oncolytics:¹¹

- Create one universal enrollment form for all patient assistance programs
- Engage with private payers to improve access to oral oncolytics, streamline administrative processes, and equalize coverage between formulations
- Move all oral oncolytics under the medical benefit
- Establish provider reimbursement for oncology treatment planning
- Create an oncology-specific benefit
- Expand access to oncology in-office pharmacies and ensure private payers contract with such entities
- Develop payer messages regarding the potential issues surrounding the use of episode-of-care payment models in oncology

With approximately 25 percent of the current oncology drug pipeline comprised of oral formulations, the authors of this report point out that oral oncolytics will only continue to grow in the marketplace, while also citing that the existing “healthcare system is ill-equipped” for these future therapies. By adopting and implementing the best practices outlined in their report, the authors suggest that some of the access challenges may be mitigated.¹¹

To access the report on “Oral Oncolytics—Addressing the Barriers to Access and Identifying Areas for Engagement,” please use the following link:

<http://www.communityoncology.org/wp-content/uploads/AvalereCOA-Oral-Oncolytics-Study-Summary-Report.pdf>

CMS Provides New Resource on the Elimination of Consultation Codes Under Medicare

On February 24, 2010, CMS revised the “Consultation Services Payment Policy” by providing additional guidance and clarification on the elimination of consultation codes and services payments.¹² Specifically, CMS released a new reference resource, outlining key questions and answers for physicians on the changes with respect to the consultation services and codes.

In the calendar year 2010, per the Medicare Physician Fee Schedule (MPFS)

final rule, CMS eliminated the payment of all Current Procedural Terminology (CPT) codes for consultation services across multiple sites of services, including the physician office, hospital inpatient department, and hospital outpatient department. The only exception to this new regulation involves G-codes under the Healthcare Common Procedures Coding System (HCPCS) for telehealth consultation, which continues to be recognized.¹²

12. <http://www.cms.hhs.gov/MLN MattersArticles/downloads/MM6740.pdf>

The elimination of the consultation codes was implemented by CMS in a budget neutral manner, which did not increase nor decrease Medicare payments. Specifically, CMS accomplished budget neutrality by:¹²

- Increasing the work relative value units (RVUs) for new and established office visits
- Increasing the work RVUs for initial hospital and initial nursing facility visits
- Incorporating the increased use of these visits into practice expense (PE) and malpractice RVU calculations

The updated guidance is an important tool for oncology practices to review carefully to better understand these significant changes, which can answer questions such as:¹³

- Does this policy apply to other Medicare products, such as Medicare Advantage?
- How will Medicare contractors handle claims for subsequent hospital care CPT codes that report the provider's first E/M service furnished to a patient during the hospital stay?
- How should providers bill for E/M services that cannot be described by any CPT E/M code that is payable by Medicare?

- Because CPT consultation codes are no longer recognized by CMS for payment, is the definition of transfer of care no longer relevant?
- When is it appropriate for providers to report critical care services in the context of furnishing an E/M service that could be described by a CPT consultation code?
- What constitutes a new versus an established patient? Can a provider bill an office/outpatient new patient visit code and/or an initial hospital care service code for a patient seen within the past three years but for a new problem?
- Will Medicare contractors accept the CPT consultation codes when Medicare is the secondary payer?
- Can a provider provide an advance beneficiary notice (ABN) to the beneficiary and then bill his or her charge for the consultation after the consultation is billed and denied by Medicare?

To access the new reference resource, "Questions and Answers on Reporting Physician Consultation Services, please use the following link:

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE1010.pdf>

13. <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE1010.pdf>

Xcenda will continue to monitor related updates. For any questions or more information, please contact Xcenda at (800)788-9637 ext. 6259.

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