



Wednesday, October 22, 2014

## In this Issue:

### **New COA Report Finds 82% Increase in Cancer Clinic Closings Since 2010**

The Community Oncology Alliance this week released its fifth annual Community Oncology Practice Impact Report, which demonstrates alarming trends in community cancer care, including an 82 percent increase in community cancer clinic closings and an 143 percent increase in hospital consolidations since COA's inaugural report in 2010. [Read below](#)

### **PhRMA Files Suit Challenging HHS Orphan Drug Regulation**

PhRMA filed a suit against the Department of Health and Human Services (HHS) last week, in attempt to block an "interpretive rule" that would expand 340B drug discounts to a majority of orphan drugs. [Read below](#)

### **Aunt Minnie Op-Ed: Payment parity in radiation therapy best serves cancer patients**

A recent op-ed in Aunt Minnie disputes a new report claiming that Medicare reimbursement rates for freestanding oncology facilities far surpasses those for hospital-based centers and warns that additional cuts to radiation oncology will compromise patient access to care. [Read below](#)

### **JAMA Articles Illustrate Division Over Lung Cancer Screening**

Conflicting articles published in JAMA Internal Medicine diverged on the necessity of CT lung cancer screening for high-risk adults enrolled in Medicare, intensifying debate regarding the procedure's coverage by the social insurance program. [Read below](#)

### **AMA Sends Blueprint to Strengthen the Meaningful Use Program to CMS**

On October 14, the American Medical Association sent a letter to the Centers for Medicare and Medicaid Services and the Office of the National Coordinator for Health Information Technology outlining a recommended blueprint for strengthening and Meaningful Use program for Electronic Health Records. [Read below](#)

## New COA Report Finds 82% Increase in Cancer Clinic Closings Since 2008



The Community Oncology Alliance (COA) this week released its fifth annual [Community Oncology Practice Impact Report](#), which demonstrates alarming trends in community cancer care, including an 82 percent increase in community cancer clinic closings and an 143 percent increase in hospital consolidations since COA began collecting data for this annual report.

According to the COA report, since 2008, 1,447 clinics have experienced the following:

- 313 Clinics Closed
- 395 Practices Struggling Financially
- 46 Practices Sending Patients Elsewhere
- 544 Practices Acquired by Hospitals
- 149 Practices Merged or Acquired

The report sites “insufficient Medicare reimbursement, exacerbated by the sequester cut to cancer drugs, and higher reimbursements and drug margins available to hospitals” as the reasons for hospital consolidations. COA further sites 340B drug discounts as a reason for consolidations, reporting, “we found that over the past two years 74.5% of the acquisitions of community oncology clinics were by hospitals with 340B drug discount pricing.”

“This report is a long-needed wake-up call to Congress and the President,” said COA executive director Ted Okon in a [press statement](#). “Our nation faces a tragic cancer care crisis that is adversely affecting those Americans who are falling through treatment cracks and paying higher prices for cancer care. It’s ironic that despite all the obstacles that policy makers have thrown at them, community oncologists are actually pioneering innovative healthcare payment reform.”

The COA practice impact database is compiled and updated from data obtained from public and private sources to the best knowledge of COA.

To access the full COA report, [click here](#).

## PhRMA Files Suit Challenging HHS Orphan Drug Regulation



PhRMA filed a suit against the Department of Health and Human Services (HHS) last week, in attempt to block an “interpretive rule” that would expand 340B drug discounts to a majority of orphan drugs.

The “interpretive rule,” which was issued this July by the Health Resources and Services Administration (HRSA) reverses an existing discount exemption for all orphan drugs – pharmaceuticals developed specifically to treat a rare medical condition – regardless of their use. However, the rule establishes that only orphan drugs

utilized to treat orphan conditions should receive such exemptions.

The drug industry trade group asserts that HRSA’s new regulation is unlawful, citing recent legal precedent. In May, the U.S. District Court for the District of Columbia invalidated an earlier rule that also had given 340B discounts to orphan drugs used to treat non-orphan conditions.

However, HRSA is steadfast in their belief that orphan drugs were able to obtain orphan status solely because of their ability to treat rare disease. Therefore, the exemptions must only be instated for drugs serving their original purpose.

The 340B drug discount program – which requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices – has been a topic of heated debate since its inception. The Affordable Care Act expanded the range of health care providers that could be eligible to buy drugs through the 340B program, but exempted orphan drugs from the discounts entirely.

To view the interpretive rule, [click here](#).

## Aunt Minnie Op-Ed: Payment parity in radiation therapy best serves cancer patients

Dr. Paul Wallner, senior vice president of 21st Century Oncology, recently penned an [op-ed in Aunt Minnie](#) responding directly to a recent report claiming that Medicare reimbursement rates for freestanding oncology facilities far surpass those for hospital-based centers.

Dr. Wallner writes, “Regrettably, the researchers exclusively analyzed data from patients treated between 2004 and 2009. While the findings could be accurate for

that historical era, the study provides a grossly inaccurate and misleading picture of Medicare payments to freestanding radiation oncology facilities over the past five years.”

The op-ed further points out Medicare payments to freestanding oncology facilities are substantially lower than payments to hospital-based radiation oncology facilities due to dramatic cuts experienced by freestanding centers since 2009.

He also warns that the proposed cuts of 4 percent to radiation oncology and 8 percent to freestanding radiation therapy centers in the 2015 Medicare Physician Fee Schedule Proposed Rule – on top of the 20 percent cut in Medicare payments freestanding centers have experienced in the past ten years – could jeopardize patient choice and patient access.

Instead, Dr. Waller recommend a site-neutral approach to ensure Medicare pays the same amount for the same service despite the clinical setting. This could prevent a greater shift of patients to the hospital setting, where costs are nearly 20 percent higher.

He adds, “The radiation oncology community would be best served by a new payment system that ensures stability in payments under a fee schedule that pays the same rate regardless of point of service.”

To read the op-ed in its entirety, [click here](#).

## JAMA Articles Illustrate Division Over Lung Cancer Screening

Conflicting articles published in JAMA Internal Medicine diverged on the necessity of CT lung cancer screening for high-risk adults enrolled in Medicare, intensifying debate regarding the procedure’s coverage by the social insurance program.

In an editorial, Douglas Wood of the University of Washington emphasized inconsistencies in policy, as preventative screenings are covered for younger patients, but not for the older, higher-risk Medicare population. Virginia Commonwealth University researchers, however, urged caution in a recent article, citing ambiguous data and potential risks associated with CT screening for older Americans.

The Centers for Medicare & Medicaid Services (CMS) is currently deliberating whether to cover the screening for a specific population of Medicare beneficiaries who are at high risk of developing lung cancer because of heavy smoking history. A committee commissioned by CMS to review the evidence concluded last spring with low to intermediate confidence that “there is adequate evidence to determine if the benefits outweigh the harms” in the Medicare population.

The agency is yet to issue a final rule.

“Cancer screening is a little like buying insurance or paying taxes,” said Wood, in support of the screenings. “A large number of people participate and may not directly benefit (or may even be harmed to some degree) to provide a life-saving benefit for a smaller number of people.”

Wood’s position is fortified by a coalition of more than 60 patient-advocacy and medical groups – including the American Cancer Society and American Cancer Society Cancer Action Network – that urged Medicare to cover the exams for certain high-risk smokers and ex-smokers ages 55 to 80 last month.

“There has been an undervaluing of the benefits and the key benefit is the ability to avoid a lung cancer death,” said Richard Wender, the ACS’s chief cancer control officer.

However, the VCU researchers aligned more closely with CMS’s initial findings, asserting that current data remains too inconclusive to invest in CT screening for Medicare populations.

Specifically, the researchers note that evidence revealing that low-dose CT screening significantly reduces lung cancer in high-risk adults comes primarily from a single 2011 study, in which most of the study subjects were below Medicare age. In other words, the population was not representative, and therefore not indicative of its success among older Americans.

The VCU team also raised questions regarding potential undesirable effects of CT screening, including false-positive results, anxiety, radiation exposure and overdiagnosis — detection of cancers that won’t produce symptoms before death.

“Our call for prudence is not a display of insensitivity to the approximately 160,000 people in the United States who die annually from lung cancer,” wrote the VCU researchers. “It is fair to ask whether low-dose CT screening would add incremental benefit over tobacco control and would save enough additional lives to offset the harms it would cause.”

Read Douglas Wood’s editorial [here](#).

Read the VCU researcher’s article [here](#).

## AMA Sends Blueprint to Strengthen the Meaningful Use Program to CMS

On October 14, the American Medical Association (AMA) sent a letter to the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator

for Health Information Technology (ONC) outlining a recommended blueprint for strengthening the Meaningful Use (MU) program for Electronic Health Records (EHR).

The AMA warns that some existing MU requirements decrease the efficiency of patient visits, and encourages increased flexibility in the MU program to ensure it achieves its desired result of improved patient care coordination and information sharing.

The letter further warns that the costs associated with MU are a deterrent to the program, writing, “There is growing concern that the cost of the MU program for many physicians far exceeds not only the maximum incentives offered under MU, but also the cost estimated by CMS to purchase and maintain an EHR. Furthermore, physicians have to incur significant expenses to update their EHRs, purchase additional software to share data, or perform other basic functions that many believed were included in the initial price of the system. More concerning is that many physicians are now incurring costs to replace EHRs that do not perform.”

The AMA urges CMS and ONC to more closely study total costs of MU compliance to understand its impact on physician practices.

If the challenges outlined by AMA are left unaddressed, AMA warns they may be:

- Jeopardizing patient safety
- Increasing administrative burden
- Interrupting access to patient information and hindering care coordination
- Decreasing efficiency
- Inhibiting access to innovative technology
- Hindering other innovative solutions
- Placing undue costs on physicians
- Slowing the movement to alternate payment/delivery models of care

In closing, the AMA strongly recommends the following changes to the MU program:

- Adopt a more flexible approach for meeting MU
- Expand hardship exemptions for all MU stages
- Improve quality reporting
- Address physician EHR usability challenges

To access the AMA letter and blueprint in its entirety, [click here](#).