### American Society of Clinical Oncology Policy Statement on Medicaid Reform

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#### **EXECUTIVE SUMMARY**

Entitlement reform is likely to dominate the discussion of the upcoming Congress, and the Medicaid provisions of the Affordable Care Act (ACA) are being implemented this year. The American Society of Clinical Oncology (ASCO) has an opportunity to help shape the debate about how cancer care will be delivered to our most vulnerable patients. As Medicaid continues to evolve in the post-ACA era, ASCO sets forth the following guiding principles with the goal of providing access to high-quality cancer care for all low-income individuals.

#### **Principles**

- 1. No individual diagnosed with cancer should be without health insurance that guarantees access to high-quality cancer care delivered by a cancer specialist.
- 2. Patients with cancer who have Medicaid should receive the same timely and highquality cancer care as patients with private insurance.
- 3. Medicaid payments should be sufficient to ensure that Medicaid patients can have access to quality cancer care.
- 4. Patients with cancer who have Medicaid should not face insurance barriers to clinical trial participation.

ASCO advocates for the highest-quality care for our most underserved and vulnerable patients with cancer. Thus, Medicaid reform is among our top priorities. To that end, we put forward the following specific policy recommendations, some of which can be advanced as part of the rulemaking process and others as part of federal and state legislation.

#### **Policy Recommendations**

- 1. Expand insurance coverage for individuals below the federal poverty level (FPL) in all 50 states.
- 2. Ensure oral parity for patients with Medicaid coverage and include oral and intrave-

- nous cancer therapies, as well as supportive care medications, as exempt services for cost-sharing purposes (similar to preventative services, services provided to hospice patients, and so on).
- 3. Extend clinical trial protections included in the ACA to patients with Medicaid coverage, and allow patients with Medicaid coverage to cross state lines to participate in those trials.
- 4. Eliminate artificial barriers between current Medicaid beneficiaries and newly eligible beneficiaries, and apply ACA final-rule mandates for cancer screening and diagnostic follow-up without copay for all Medicaid beneficiaries.
- 5. Require coverage for genetic testing, without deductibles or copays, in any patient deemed at high risk for an inheritable cancer risk syndrome as defined by published guidelines.
- 6. Improve the 340B Drug Pricing Program so that it is used for its original intent: to incentivize care for the uninsured and underinsured and patients with Medicaid coverage, regardless of care setting.
- 7. Eliminate variation between Medicare and Medicaid physician payment rates for cancer diagnosis and treatment by raising Medicaid payments to Medicare rates.
- 8. Tie state flexibility in running Medicaid programs to the requirement to meet predefined cancer quality metrics.
- 9. Allow oncology practices to be designated as medical homes, and develop expanded reimbursement for care coordination and patient education for oncology practices.

#### **BACKGROUND**

The ACA was designed, in part, to provide insurance coverage to the millions of Americans who are currently uninsured. This is primarily accomplished through Medicaid expansion for all uninsured adults with a family income below 133% of the FPL. The federal government provides 100% of the costs of expansion from 2014 to 2016. The proportion of expansion costs provided by the federal government would decrease to 90% by 2020. Estimates of the number of new enrollees, associated costs of care, and number of physicians required to provide care in the face of increased demand are highly variable. However, the Congressional Budget Office estimates that 16 million additional individuals will obtain care through Medicaid and the Children's Health Insurance Program, with federal costs reaching nearly \$100 billion by 2019. A Kaiser Family Foundation study suggests that approximately one sixth of these individuals are in poor or fair health, more than 60% have no usual source of health care, and one third have at least one chronic health condition.<sup>2</sup> Approximately 160,000 are believed to have an ongoing cancer diagnosis, although all of these figures are likely underestimates, given the lack of contact these individuals have with the health care system.

It is important to point out one area of confusion about the Medicaid expansion, because it governs many policy recommendations. The ACA created two groups of Medicaid beneficiaries: those who qualify for Medicaid by rules in effect in each state before the ACA (traditional Medicaid) and those who qualify because of the expansion of Medicaid (expanded Medicaid) under the ACA. For patients in traditional Medicaid, states have some latitude about what is included in the benefits package as governed by the Deficit Reduction Act of 2005 (Public Law 109-171). For the expanded Medicaid group, the states must use a benchmark plan as established by the ACA to define benefits. Before the ACA, only 12 states had experience using benchmark packages to establish Medicaid benefits.<sup>3</sup> In practice, this means that the two populations may have different benefits. Many of our recommendations will apply to one group versus the other, and we will make this clear in the text. Regardless, one of our recommendations is to eliminate this artificial barrier and harmonize the Medicaid program in each state under one set of benefit rules to avoid the inevitable confusion this will cause for providers and patients.

The potential positive impact of Medicaid expansion on health outcomes was demonstrated in a quasi-experimental study of states that expanded Medicaid to cover previously ineligible adults between 2000 and 2005 compared with adjacent states that did not.<sup>4</sup> In the 5 years after expansion, county-level all-cause mortality decreased in the Medicaid expansion states by approximately 6%. In addition, delays in care were significantly reduced in the expansion states, and self-reported health increased significantly.<sup>4</sup>

People with cancer, for whom the costs of evaluation and treatment can be extraordinarily high, are particularly in need of insurance coverage to allow for timely diagnosis and high-quality treatment. For example, facilitating Medicaid enrollment has been reported to increase the likelihood of enrollment among women diagnosed with breast cancer at early stages of disease. Furthermore, individuals with Medicaid coverage before a cancer diagnosis fare better than those without insurance at the time of diagnosis. Bradley et al<sup>6</sup> found that individuals enrolling in Medicaid after a cancer diagnosis (and possibly because of a cancer diagnosis) were more likely to present with advanced-stage cancer than were those enrolled in Medicaid before a cancer diagnosis. These results suggest that more restrictive Medicaid eligibility policies, resulting in later enrollment in Medicaid, may affect access to care for enrollees with cancer and thus lead to later disease stage at diagnosis and worse outcomes. In addition, because costs for

cancer treatment are greater for those diagnosed with more advanced disease, <sup>7</sup> improved access to Medicaid before a cancer diagnosis also may be cost saving.

Published literature on the impact of Medicaid coverage, compared with being uninsured or having private insurance coverage, on cancer diagnosis, treatment, and outcomes presents mixed results. Several studies have shown concerns with the quality of care that Medicaid patients receive throughout the cancer care continuum. For example, data from the National Cancer Data Base revealed that individuals with Medicaid were significantly more likely to be diagnosed with cancer at later (stage III or IV) versus earlier stages (stage I) compared with privately insured patients for 11 of 12 cancer sites examined. The largest negative impacts of Medicaid were seen for cancers that can be diagnosed early through appropriate screening, such as breast cancer (odds ratio, 2.7) and melanoma (odds ratio, 3.3).

However, a number of studies have reported similar treatment patterns and outcomes among Medicaid and privately insured patients diagnosed with cancer after adjusting for potential confounders. 18-21 For example, Chen et al<sup>22</sup> reported similar rates of adherence to breast cancer quality indicators for patients treated at a public hospital compared with a broader cohort of patients receiving care in five metropolitan areas. Similarly, among individuals diagnosed with breast or colorectal cancer at safety-net hospitals, those with Medicaid did not have increased risk of advanced-stage cancer at diagnosis compared with those with private insurance. Uninsured patients were significantly more likely to be diagnosed with advanced cancer than were insured patients. 18 The authors commented that at this institution, many barriers to care for Medicaid patients had been removed; thus, the expected new Medicaid enrollees under the ACA are likely to experience outcomes similar to those of other insured patients at safety-net hospitals. In addition to hospital- or health system-level barriers experienced by Medicaid beneficiaries diagnosed with cancer, patient-level factors including differences in health behaviors (such as smoking), socioeconomic status, education, and comorbidities may also affect access to care and treatment outcomes.<sup>23,24</sup>

Despite this, cancer treatment at safety-net hospitals may not be equal in quality to other hospitals. Bradley et al<sup>25</sup> suggested that outcomes for individuals with breast cancer treated at safety-net hospitals may worsen after Medicaid expansion if these hospitals do not also receive increases in reimbursement and staffing levels. Others have also speculated that barriers to timely cancer diagnosis and treatment for Medicaid enrollees likely reflect, at least in part, low Medicaid reimbursement levels for medical care providers in many states. Studies of Medicaid reimbursements in other clinical areas indicate that increased reimbursements are associated with increased access to care and improved patient outcomes<sup>26-28</sup>; however, it is uncertain whether the relationship between Medicaid reimbursement and patient outcomes in these studies would also be found in cancer care. Although there is little information regarding the effects of Medicaid reimbursement on cancer outcomes, a recent study reported that increased Medicaid reimbursement for office visits was associated with increased likelihood of cancer screening among Medicaid beneficiaries.<sup>29</sup> Increased reimbursement for cancer diagnostic and treatment services may similarly improve outcomes for Medicaid beneficiaries diagnosed with cancer.

The purpose of this article is to provide concrete policy recommendations that need to be considered and addressed as Medicaid evolves in the post-ACA era, with the goal of providing access to

high-quality cancer care for all low-income individuals. We understand that many of the recommendations in this statement are potentially applicable to other chronic care populations, and we hope this statement will serve as a model for other specialty societies to develop advocacy around Medicaid reform.

#### **POLICY RECOMMENDATIONS**

# Expansion of Insurance Coverage for Individuals Below Poverty Level

Current situation. The Supreme Court ruled that Congress does not have the power to mandate that states either provide coverage through Medicaid or expand Medicaid. Although individuals with incomes at or above 100% of the FPL will qualify for subsidies in the health insurance exchanges established by the ACA, those below the poverty level do not qualify for federal subsidies. Therefore, if these individuals live in a state without expanded Medicaid coverage, they may remain without any health insurance coverage. As of this publication, 28 states, including the District of Columbia, were expanding Medicaid, 21 were not, and the remaining two were "open debate".<sup>30</sup>

Recommendation for change. All states should either expand their Medicaid program to, at a minimum, provide coverage for individuals with incomes below the FPL, or they should come up with an alternative strategy that provides comprehensive subsidized health coverage that ensures, among other benefits, access to high-quality cancer care, measured by cancer-specific quality metrics, delivered by a cancer specialist. We strongly encourage states to take advantage of the enhanced federal match (100% through 2016 and phasing down to 90% in 2020) available to them if they expand Medicaid eligibility to 133% of the FPL (because 5% of income is not counted, Medicaid eligibility will actually be 138% of the FPL). This enhanced match would not be available to states if they expanded to just at or below the poverty level. If they choose not to do this, an alternative strategy should be in place to ensure subsidized health care for individuals with incomes below 100% of the FPL, so no group is left without subsidized health care coverage options.

#### **Oral Drug Parity**

Current situation. States are allowed to charge higher copayments to Medicaid recipients with family incomes above 150% of the FPL (\$17,505 for one person and \$35,755 for a family of four in 2014). The amount of cost sharing cannot be more than 20% of the cost (Medicaid payment amount) of the drug. Total cost sharing cannot be more than 5% of the family's income.

Given the price of many oral anticancer therapies (\$5,000 per month is not uncommon) and supportive care medications, a 20% copay, even if capped at 5% of the family income (\$840 for one person and \$1,730 for a family of four), would be cost prohibitive and would discourage the use of these life-prolonging and, in many cases, life-saving drugs by these vulnerable patients.

Recommendation for change. Protect access to orally administered cancer medications by setting out-of-pocket expenses equal to those for other intravenous (IV) or injected anticancer medications. Alternatively, include oral and IV cancer therapies and supportive care medications as exempt services for cost-sharing purposes, as are other services such as preventive and hospice care

services. These limits should be applied to both the traditional and expanded Medicaid populations.

#### Clinical Trials

Current situation. The cost of conducting a clinical trial has several components. The medical or routine patient care costs for services provided to patients in clinical trials, such as physician visits, laboratory tests, and radiology examinations, are reimbursed to a variable extent by third-party payers. Several studies have found that the incremental costs to the health care system for treating patients in clinical trials are minimal. 31-34 Importantly, when coverage laws were enacted in a limited number of states, participation in early-phase clinical trials increased.<sup>35</sup> The ACA recognized this and therefore included Section 2709 (codified as 42 USC §300gg-8), which imposes requirements on group health plans and health insurance issuers offering individual or group health insurance products to provide coverage of routine patient care costs associated with approved clinical trials. These federal requirements apply to plans and coverage sold after 2013 in the individual and small-group markets, as well as to large-group plans, including self-insured Employee Retirement Income Security Act plans. The requirement will also apply to health plans offered under the Federal Employees Health Benefit Program. The law provides an exemption for group health plans (which includes single-employer plans and multiemployer plans, whether insured or self insured) or health insurance coverage that was in effect as of March 23, 2010 (the date of the ACA enactment). These grandfathered plans are not required to offer clinical trial coverage if the plan or insurance has not reduced benefits or increased costs to enrollees since March 23, 2010. The number of grandfathered plans is expected to decrease

The Medicaid program was not specifically included in this requirement. Given the particularly poor accrual of under-represented racial and ethnic minority patients in clinical trials,<sup>36</sup> this oversight places these patients, who are over-represented in the Medicaid program, at an even greater disadvantage for clinical trial enrollment. This prevents access to clinical trials for low-income Medicaid enrollees and will impede our ability to learn about potential important differences in response to, or tolerance of, treatment in this nation's racially and ethnically diverse patient population.

Recommendation for change. Include Section 737 (ie, Participation by Medicaid Beneficiaries in Approved Clinical Trials) from S. 2474 of the Health Equity and Accountability Act of 2012 in any Medicaid reform legislation, so Medicaid enrollees are granted coverage of routine patient care costs associated with approved clinical trials. This should include a requirement that states allow Medicaid patients to cross state lines to receive care in an approved clinical trial. Because it is unclear whether the clinical trial provisions in the ACA apply to the expanded Medicaid population, it should be made clear that this provision would apply to both the traditional and expanded Medicaid populations.

#### Cancer Screening and Genetic Testing Under Medicaid

Current situation. Coverage of preventive services approved by the US Preventive Services Task Force with a grade A or B recommendation is currently required without copay in the Essential Health Benefits Package of the ACA. In addition, such coverage is extended to diagnostic procedures performed as a result of the screening test (eg,

removal of a polyp during a screening colonoscopy). However, for reasons that are not clear, this provision applies only to those Medicaid patients who are newly eligible under the ACA Medicaid expansion and does not apply to traditional Medicaid beneficiaries. The ACA does provide an incentive (1% increase in federal medical assistance percentage) for states that provide coverage for their traditional Medicaid recipients.

To clarify the magnitude of this issue, all states cover services such as breast, cervical, and colon cancer screening, but 10 to 15 states require a copay. For services like genetic counseling for hereditary breast cancer (grade B recommendation), only 30 states provide coverage; of these, eight require that patients be charged a copayment for this service.<sup>37</sup>

Another issue is that although genetic counseling related to hereditary breast cancer will be covered because it has a USPSTF B rating, the law is not specific about covering the cost of genetic testing for a BRCA mutation. In addition, no other cancer risk syndromes are specifically mentioned by the law. Pharmacologic therapy for breast cancer prevention has a USPSTF B rating, and therefore, the ACA provides coverage and prohibits cost-sharing requirements for women at increased risk for breast cancer.<sup>38</sup> However, there is no mandate for coverage of risk-reducing surgery for patients found to carry a genetic mutation, despite research showing the cost effectiveness of such procedures. 39-42 It has been well documented that prophylactic hysterectomy with bilateral salpingo-oophorectomy reduces the risk of endometrial and ovarian cancers in women with Lynch syndrome. 43-45 Therefore, failure to cover genetic testing and riskreducing surgeries and medications will perpetuate the health disparities prevalent in the Medicaid population. 17,46

Of note, the USPSTF has now issued a draft recommendation (grade B) for annual screening for lung cancer with low-dose computed tomography in persons at high risk for lung cancer based on age and smoking history. This screening will likely disproportionately benefit poorer patients, many newly covered by Medicaid, who have higher smoking rates than more affluent patients.

*Recommendation for change.* Clarify that any Medicaid benefits for any class of Medicaid beneficiary must include the following:

- Elimination of artificial barriers between current Medicaid beneficiaries and newly eligible beneficiaries and application of ACA final-rule mandates for screening and diagnostic follow-up without copay for all Medicaid beneficiaries.
- Coverage for appropriate treatment for any cancer found as a result of a covered cancer screening service.
- Coverage for genetic testing (not just genetic counseling), without deductibles or copays, in any patient deemed at increased risk for an inherited cancer risk syndrome as defined by published guidelines.
- Coverage for risk-reducing therapies, including surgeries and medications, in patients who have an inherited cancer risk syndrome.

#### **Drug Pricing**

Current situation. The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Nonprofit hospitals can qualify for these reduced prices primarily by having a disproportionate share hospital adjustment of 11.75% or greater. The drug rebate applies to all patients receiving care in these hospitals, not just the

poor or uninsured. Community oncology practices are not eligible for the 340B program unless they are owned by a hospital that qualifies for 340B.

Recommendation for change. Policymakers should consider changes to the 340B program so that it is used for its original intent: to incentivize care for the uninsured and underinsured and Medicaid patients, regardless of care setting. ASCO continues to be involved in this area and has developed specific recommendations for 340B reform. 47

#### Payment Reform

Current situation. The Kaiser Family Foundation published a report in 2012 on the Medicaid-to-Medicare fee index. The Medicaidto-Medicare fee index measures the Medicaid physician fees relative to Medicare fees of each state. Fee indexes for all services range from a low of 0.37 in Rhode Island to a high of 1.34 in North Dakota. On average, the national fee index is approximately 0.7.48 These rates are based on the traditional Medicaid fee-for-service program and do not reflect patients newly insured under Medicaid through the ACA. Private insurers typically reimburse more than either program. As a result, many physicians are turning Medicaid patients away, citing that reimbursement from Medicaid fails to cover the cost of care. A recent physician survey finds that only 72% of specialty physicians are accepting new Medicaid patients, compared with 91% who are accepting new Medicare patients. 49 The lack of participating physicians leaves many patients scrambling to find a physician or obtaining their care in emergency departments. This is especially problematic for patients with cancer, because delay in treatment may have life-threatening consequences. The ACA seeks to add an additional 16 million people to the Medicaid program, compounding the problem further. Expanding the number of community-based oncologists who accept Medicaid patients would not only improve access but also increase patient choice and autonomy. However, without significant changes to the current Medicaid system, such an expansion is unlikely to occur.

Recommendation for change. The Medicaid payment policy, like the policies of Medicare and private payers, needs to be redesigned. We agree with the principle laid out by several groups that Medicaid should focus on and reward care that emphasizes the quality rather than the amount of care provided. To this end, we support a payment model that meets the following standards:

- Increases Medicaid payment rates to equal those for Medicare.
- Creates a leadership role for oncologists in developing and testing cancer payment reforms.
- Provides incentives to address meaningful quality metrics specific to patients with cancer.

At the same time, state flexibility in running Medicaid should be coupled with meeting predefined cancer quality outcomes for the Medicaid patient population. Failure to meet quality metrics should be cause for the federal government to intervene. These recommendations are consistent with the recently published Institute of Medicine (IOM) report on delivering high-quality cancer care, where development of meaningful quality measures for cancer care with a focus on outcome measures and performance targets is emphasized.

#### **Medical Homes**

Current situation. The ACA includes provisions for medical homes. Under Medicaid, states are authorized to make medical assistance payments at an enhanced federal match to a team of health professionals providing a comprehensive set of medical services, including care coordination for patients with chronic conditions. In

designing its Medicare medical home demonstration, the Centers for Medicare and Medicaid Services expected to pay \$27 to \$100 per member per month, depending on the severity of the patients' illnesses and the level of medical home for which the practice qualifies. These payments would be made in addition to traditional fee-for-service payments. Currently, medical home designations apply only to primary care facilities, although the services that define a medical home, including care coordination, patient and family education, and aggressive management of chronic conditions, are the same services that patients with cancer require and in part define quality cancer care.

Patients with cancer need multidisciplinary, coordinated care from the onset of diagnosis through treatment, survivorship, and end of life. According to the 2013 IOM report "Delivering High Quality Cancer Care, Charting a New Course for a System in Crisis," the cancer care team should provide patients and their families with understandable information on cancer prognosis, treatment benefits and harms, palliative care, psychosocial support, and estimates of the total and out-of-pocket costs of care. End-of-life care should be delivered in a manner that is consistent with the patient's needs and values. <sup>50</sup>

In addition, many patients with cancer—especially minority and underserved populations-suffer from multiple comorbid conditions. Early detection and treatment not only save lives but also reduce total cancer care expenditures. Many prevention programs, such as screening and smoking cessation, reduce death rates as well as decrease overall health care costs. As such, the medical home model provides an excellent framework for the care of patients with cancer and, in particular, populations that currently experience disparities in cancer prevention, screening, care, and outcome. The IOM report calls for the development of innovative programs, identification and dissemination of effective community interventions, and provision of ongoing support to existing successful community interventions as key to eliminating disparities in cancer care. The report also calls for improving clinicians' use of systematically developed guidelines and increasing the measurement and monitoring of cancer care using a core set of quality measures. Cancer medical homes focused on comprehensive quality care serve as one such model not only for underserved populations but also for cancer care in general.<sup>50</sup>

A number of obstacles to achieving cancer-specific medical homes currently exist. The most important of these is a lack of adequate reimbursement for the time needed to develop, discuss, and document a treatment plan and to provide adequate time for patient education and family meetings. In addition, many oncology practices are unable to provide much needed psychosocial, nutritional, and risk-reduction services because of a lack of appropriate codes to bill for such services.

Recommendation for change. We support the following measures:

- Include coverage for cancer-related medical home pilot projects.
- Develop expanded reimbursement for care coordination and patient education by qualified cancer specialists.
- Develop expanded reimbursement for risk reduction, nutritional, and psychosocial counseling.
- Develop reimbursement methodologies for electronic communication and telephone services.
- Develop methodologies that can lower the cost of caring for Medicaid recipients with cancer, such as expansion of 340B

- pricing to eligible practices, development of group purchasing organizations among medical homes, and participation in the Federal Tort Reform Act.
- Incorporate or adopt cancer-specific quality metrics as measures of the quality of care delivered among medical home providers.
- Analyze cost savings of cancer-related medical homes through improved coordination of care, reduced emergency room visits, decreased hospitalizations, diminished use of unnecessary procedures and treatments, and increased use of palliative care and hospice services at the end of life.

#### **DISCUSSION**

Policy debates over Medicaid reform in the post-ACA era threaten to exacerbate disparities in cancer care. Medicaid is far from perfect, and all stakeholders have legitimate concerns with the program in its current form. ASCO believes that no individual diagnosed with cancer should be without health insurance that guarantees access to high-quality cancer care, which includes care delivered by a cancer specialist, as well as access to clinical trial participation. For clinical practices, the program reimburses at substantially lower rates compared with Medicare and is not sustainable. For federal and state officials, the program threatens yearly budgets and adds to long-term debt concerns. However, for our patients, the program is more than a line item—it is a lifeline. This leaves us with a program that saves lives but is disliked by many health care providers and their financial administrators and is threatening state and federal budgets.

The issue on which almost everyone agrees is that Medicaid must be reformed. The recommendations presented in this statement offer several important ways in which this reform should take place. It is hoped that these recommendations provide a foundation on which the oncology community can make its voice heard, not only in Washington but also in statehouses across the country.

## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

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#### **AUTHOR CONTRIBUTIONS**

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