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Kenneth E. Jones, CEO

(4)

Medicaid Reform in North Carolina – Ken Jones, Eastpointe CEO

Eastpointe LME-MCO is one of the nine (9) Medicaid Behavioral Health/IDD Managed Care Organizations charged with the implementation, refinement and management of North Carolina's Medicaid 1915 b/c Waiver. Eastpointe serves the third largest Medicaid population with a total of 183,000 covered lives residing in a twelve (12) county service area and have an operating budget of over $300 million. Our service population includes the most fragile of our citizens—those dealing with a severe mental illness, substance use, intellectual and developmental disabilities, and injured populations such as those with traumatic brain injury.

Eastpointe, along with North Carolina's other Public LME-MCO's, emerged from a multi-year change process that required the large scale consolidation of the old Area Programs, a dramatic change in role from provider to system manager and an absolute commitment to changing the culture of our organizations. It must be noted that LME-MCO's, as management entities, are now delivering significant benefits for your State and the citizens we serve. We offer access to quality care, competent oversight and effective provider choice all for predictable costs in the Medicaid program. We have managed to bring quality and cost containment to a significant segment of the Medicaid budget. We have initiated (and will continue to move forward with) efforts to promote integrated care programs that address the comprehensive needs of our consumers.

(Recommendations)

- Give LME-MCO's the opportunity to build on their current successes in cost containment and the management of a high quality care delivery system. LME-MCOs should be encouraged to be partners in the creation of integrated health care systems that yield better outcomes for our recipients by partnering with local hospitals, providers, and FQHC's. These partnerships will leverage the experience and resources such that the existing CCNC network and the LME-MCOs can fully implement effective models of integrated care.
- Build on existing structures and achievements in Medicaid health management (e.g. the success of the LME-MCOs and CCNC's efforts in the creation of primary care medical homes for the behavioral health/IDD.)
- Seek to mirror the success of national models such as the Pioneer Medicare ACOs which have generated success in terms of cost savings, increased quality outcomes for members, and improved accountability for both budget and program outcomes.
- Keep in mind ACO models (both provider and MCO lead) are plentiful and demonstrate the value that these partnerships can bring to our health care system. This integrated approach can support right-sizing networks and reward quality driven provider service delivery organizations. These efforts have potential to align our system's financial incentives to the benefit of our State, our communities and (most importantly) our consumers.
- For the long term financial stability of the system and the quality care of our members, Eastpointe encourages building on the demonstrated success of the MCOs.

STATEMENT

PhRMA
RESEARCH · PROGRESS · HOPE

Statement to the Joint Legislative Oversight Committee on Health and Human Services, Medicaid Reform/DMA Reorganization Subcommittee
October 20, 2014

Position: PhRMA supports the inclusion of important patient protections, as North Carolina reforms its Medicaid program. Patients (and their healthcare providers) must be able to gain access to the services and innovative treatments that best meet their individual needs and encourage continued medical progress, while at the same time improving healthcare coordination, efficiency and quality.

North Carolina is considering a Medicaid Managed Care model or an Accountable Care Organization as an option for reform. Emerging payment and delivery reforms hold promise in advancing the efficient delivery of high-quality, personalized care. ACOs and MCOs have potential to generate health system savings while improving or maintaining the quality of care provided to patients.

ACO OPTION:

If North Carolina pursues the ACO model, PhRMA believes the following best practices are essential to improving the value of care for patients and allowing continued biomedical progress:

1) An ACO should not bear full risk unless and until it has demonstrated readiness to do so as evidenced by the ability to meet licensure and patient protection requirements required of other full risk-bearing entities (e.g., health plans).

Experience with capitated providers in the late 1990s illustrates the danger of creating unintended disruptions in care if providers are not fully prepared to take on this level of financial risk. In addition, ACO programs are still relatively new, and preliminary results from current ACO programs underscore the need for ACOs to more fully develop before they are put a full financial risk. As the legislature considers steps to encourage ACOs to bear more financial risk, it will be important to ensure the organizations have sufficient information systems, delivery infrastructure, quality incentives, transparency, and mechanisms to support adoption of new tests and treatments.

2) Development and application of payment reforms, like ACOs, should follow a transparent, predictable, participatory process that encourages input from patients, providers and other stakeholders, including the pharmaceutical industry.

Stakeholders need to be confident that ACOs appropriately balance patient access, quality, cost control, and innovation. That confidence depends on an open, transparent development process

that precedes deployment, and which incorporates input from patients, physicians and other stakeholders. In addition, the state should provide transparency on how value-based payments are calculated and achieved, and in the evaluation of the impact ACOs have on the access, cost and quality of care.

3) Payment reforms should incorporate mechanisms to support patient access to the full range of treatment options and medical advances, and support the prescriber's role in selecting the best treatment for individual patients.

Value-based payment reforms can rely on annually calculated spending benchmarks or static definitions of care. As a result, they fail to account for the costs of new advances that improve patient care but can be more expensive over the short term, which creates a barrier to patient access and discourages continued innovation. New payment models must recognize and provide incentives for continued innovation, which can occur either through major breakthroughs or, more typically, through a process in which innovation builds over time and yields better outcomes for patients. Payment reforms must also preserve physician ability to appropriately tailor treatments to individual patient needs and preferences, and also support the role of physicians as patient advocates and their ability to engage in shared, well-informed decision-making with their patients.

In addition, certain payment models -- such as those that (a) give providers risk for managing a specific condition and/or base physician payment on compliance with a narrow treatment pathway, or (b) are narrowly focused around a single treatment decision and priced based on current standard of care -- can create substantial disincentives for use of innovative treatments. Prioritizing broader, patient centered payment reforms provides opportunities for improving system efficiency without compromising patient access and gives innovative treatments greater opportunity to demonstrate their value.

4) ACOs should support patient-centered care and reflect patient needs and values.

The success of ACOs should be assessed based on the extent to which it increases the value patients and their families find in the care they receive. Perceptions of value can vary considerably among patients, and the factors that patients consider may include not only improved clinical outcomes but other important factors such as quality of life and productivity. Patients are heterogeneous; they have different medical histories, comorbidities, and response to treatment.[1] Patients also have different preferences, so they do not all prioritize trade-offs between outcomes, costs, side-effects, and quality of life factors in the same way. For these reasons, ACOs must ensure that providers are not effectively penalized for a deviation from a treatment protocol to provide the most appropriate intervention to individual patients.

5) ACO development, implementation and evaluation should be based on a holistic view of patient care and system-wide perspective in setting quality outcome and cost containment goals.

Payment reforms that take a narrow, more short-sighted view run the risk of managing discrete costs in the short-term at the expense of potentially increasing costs and harming quality in the

long-run. Because most payment reforms offer providers strong financial incentives to reduce costs, providers may be driven to the lowest cost treatment among treatments that are therapeutically similar for the average patient. Such reforms would fail to capture downstream efficiencies that can be realized through practice transformation and quality improvement. In some cases, a higher cost treatment may lead to better long-term patient outcomes – which are realized outside the period in which costs are counted and quality is currently measured.

To avoid harming long-term patient health, ACOs must align short-term cost incentives with metrics that evaluate longer-term outcomes. The value of a more holistic, system-wide perspective is illustrated by evaluations showing opportunities for system-wide efficiencies (e.g., reductions in unnecessary emergency room visits and hospitalizations) while preserving patient access to provider and treatment options.[2]

6) ACOs must support continued improvement in care quality – including health outcomes – and should not sacrifice quality for the sake of cost containment.

To balance cost-containment incentives, the ACO reform design must include quality measures and incentives that support continued or improved access to high quality care.

- ACOs must include robust and meaningful quality metrics that measure patient health outcomes, quality-of-life, and functional status. Process of care measures are not sufficient in payment reforms because of their extremely limited ability to identify reductions in patient access to treatment or 'stinting' on care. Consistent with this, a number of health care stakeholders and experts have called for greater reliance on outcomes-driven measures, including intermediate outcomes and patient reported outcomes, (or adequate surrogates) to help ensure the use of clinically appropriate treatment options.[3]
- ACOs should give providers meaningful incentives to improve quality. These incentives should be equal or greater to any incentives to reduce costs.
- Additional quality measures are needed to support broad payment reform. In many areas of medicine, measures have not yet been developed to enable a meaningful evaluation of, and incentives for, care quality in alternative models.[4] Stakeholders have identified significant gaps in measures of clinical and patient-reported outcomes, such as quality of life, functional status, and patient experience of care.
- Quality incentives should not conflate cost containment tools with quality measures. Performance measures or provider activities that directly relate to cost containment goals (e.g., efficiency measures or incentives for pathway adherence) reinforce new payment models' inherent cost containment incentives and therefore should not be among the quality measures or activities used to protect patients in value-based payment models.

7) If the ACOs incorporate clinical protocols, they must be grounded in solid evidence from peer-reviewed literature.

It is vital that pathways, guidelines, and value frameworks informing payment reforms support informed physician-patient decision-making from the range of treatment options and are based on well-researched, methodologically rigorous evidence. As observational data and non-experimental research designs become increasingly common via expanded electronic databases,

there is a notable lack of agreement on what constitutes good research and solid evidence upon which to make foundational changes to the health care system. Transparency of the evidence base upon which any payment reform is designed – including the cost and quality metrics – is essential; this evidence base must be kept up to date with advances in standards of care and medical technology.

MEDICAID MANAGED CARE MODEL

If, however, policymakers select a Medicaid managed care model to reform the fee-for-service system in North Carolina, PhRMA strongly encourages the following patient protections be incorporated:

a) **Protections to assure continuity of care for beneficiaries with chronic conditions.** Require continuity of coverage for patients with ongoing medication needs to treat and manage their chronic condition. Specifically, require continued coverage for a maintenance drug prescribed within the last six months —even if the drug would otherwise be non-preferred or subject to a prior authorization requirement—for as long as the patient's physician continues to prescribe the medication.

b) **Require Medicaid PDLs and MCO formularies to be comprehensive—covering prescription drugs in all categories and classes—with additional protections for vulnerable populations.** Assure or preserve additional protections for vulnerable populations. Managed care plans should cover all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes, or at least those classes that are currently carved out of the state's Medicaid preferred drug list. Similar standards apply to Medicare Part D plans.[5]

c) **Require managed care plans' formularies to be developed and reviewed by an independent pharmacy and therapeutics committee (P&T).** A majority of the members of the P&T committee should be practicing physicians, practicing pharmacists, or both, who are licensed in the state.[v] Standards should assure that P&T committee members come from various clinical specialties that adequately represent the needs of plans beneficiaries, including an adequate number of high-volume specialists, and that specialists with expertise in a specific therapeutic area participate in formulary decisions regarding each therapeutic area. Moreover, P&T committees should meet on a regular basis (not less frequently than a quarterly basis) and have a transparent process for formulary development.[v] The P&T Committee should base its clinical decisions on the strength of scientific evidence, standards of practice,[v] and nationally accepted treatment guidelines.

d) **Allow patient choice of MCO and formulary**. Patients should be allowed to select the MCO and formulary that best suits their medical needs. All plans and their formularies must be made publicly available to patients, including being posted on the plan website, in a timely manner so that patients can make appropriate healthcare decisions.

e) **Require that Medicaid MCO formularies are no more restrictive than the coverage provided under Medicaid fee for service.** In fee-for-service Medicaid, states typically use preferred drug lists (that include drugs available to beneficiaries without the need for prior authorization) to manage drug costs while providing appropriate mechanisms to obtain coverage for non-preferred/non-formulary drugs when the physician believes it's

medically necessary. In moving drug coverage to managed care, states should require managed care plans to provide coverage that is no more restrictive than the state's preferred drug list in terms of access to covered drugs.

f) **P&T committees must review medical/formulary management tools for medical appropriateness.** Specifically, the P&T committee must review the formulary management activities, such as prior authorization, step therapy, quantity limitations, generic substitutions, and other drug utilization activities for clinically appropriateness.[6]

g) **Medical management tools (e.g. prior authorization, step therapy, quantity limits) must be consistent with "best practices."** Use of medical/formulary management tools should be based on industry standards as well as appropriate guidelines from expert patient and provider organizations,[7] including that a plan must provide response within 24 hours of a request for prior authorization or override of other medical management tools.

h) **Streamlined procedures for prior authorization and other formulary management tools.** States should establish a uniform form for plans to provide physicians seeking authorization for a covered drug, including a uniform, streamlined process for handling requests for expedited review for urgent or medical emergencies. The Affordable Care Act requires the creation of a uniform exceptions and appeals process for Part D plans.

i) **Standards for exceptions and appeals.** Managed care plans must have a fair process for handling exceptions and appeals, including expedited review (within 72 hours) for urgent or emergency medical conditions as well as continued benefits during the appeal. The exceptions and appeals process shall be transparent and made publicly available to plan members as well as posted on the plan website.

j) **Review and inclusion of new prescription drugs and other treatments and therapies.** The managed care plan will cover a newly approved FDA-approved drug until such time as the plan's P&T committee has reviewed the drug for formulary inclusion.

k) **Quality and access report.** Require the state to prepare a report assessing beneficiary access no later than 18 months after the implementation of the managed care expansion to new populations and/or for new items and services. The study should assess the impact of managed care on patient access to care, and any new barriers to use of services, including prescription drugs, created by the use of medical management or cost containment tools. The report should analyze the impact on utilization of services, quality of care, and patient outcomes. The report should closely examine use of prior authorization and other plan management tools and assess whether these tools pose an undue administrative burden for physicians and/or create barriers to needed care. The report should be submitted to the state legislature, be posted on the state Medicaid website, and the agency should provide an opportunity for public comment.

In conclusion, North Carolina's Medicaid reform proposal should not miss the opportunity to improve the quality of patient care while reducing overall healthcare costs; however this potential rests on careful development and implementation. By developing a clear process which engages a broad range of stakeholders, PhRMA urges the Committee members to incorporate patient protections articulated above. PhRMA appreciates the opportunity to provide input into the Medicaid Reform work of the legislative committee and looks forward to working closely

together on developing a solution that will meet the Committee's goals without undermining patient access, quality of care and development of beneficial new treatments.

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[3] MedPAC. "Report to Congress, Medicare and the Health Care Delivery System." June 2013. http://www.medpac.gov/chapters/Jun13_Ch03.pdf accessed July 2014.

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[5] Social Security Act (SSA) Section 1860D-4(b)(3)(G)

[6] 42 C.F.R. 423.120(b); Medicare Part D Manual: Chapter 6- Part D Drugs and Formulary Requirements. 30.1 Pharmacy and Therapeutics (P&T) Committee.

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that precedes deployment, and which incorporates input from patients, physicians and other stakeholders. In addition, the state should provide transparency on how value-based payments are calculated and achieved, and in the evaluation of the impact ACOs have on the access, cost and quality of care.

3) Payment reforms should incorporate mechanisms to support patient access to the full range of treatment options and medical advances, and support the prescriber's role in selecting the best treatment for individual patients.

Value-based payment reforms can rely on annually calculated spending benchmarks or static definitions of care. As a result, they fail to account for the costs of new advances that improve patient care but can be more expensive over the short term, which creates a barrier to patient access and discourages continued innovation. New payment models must recognize and provide incentives for continued innovation, which can occur either through major breakthroughs or, more typically, through a process in which innovation builds over time and yields better outcomes for patients. Payment reforms must also preserve physician ability to appropriately tailor treatments to individual patient needs and preferences, and also support the role of physicians as patient advocates and their ability to engage in shared, well-informed decision-making with their patients.

In addition, certain payment models -- such as those that (a) give providers risk for managing a specific condition and/or base physician payment on compliance with a narrow treatment pathway, or (b) are narrowly focused around a single treatment decision and priced based on current standard of care -- can create substantial disincentives for use of innovative treatments. Prioritizing broader, patient centered payment reforms provides opportunities for improving system efficiency without compromising patient access and gives innovative treatments greater opportunity to demonstrate their value.

4) ACOs should support patient-centered care and reflect patient needs and values.

The success of ACOs should be assessed based on the extent to which it increases the value patients and their families find in the care they receive. Perceptions of value can vary considerably among patients, and the factors that patients consider may include not only improved clinical outcomes but other important factors such as quality of life and productivity. Patients are heterogeneous; they have different medical histories, comorbidities, and response to treatment.[1] Patients also have different preferences, so they do not all prioritize trade-offs between outcomes, costs, side-effects, and quality of life factors in the same way. For these reasons, ACOs must ensure that providers are not effectively penalized for a deviation from a treatment protocol to provide the most appropriate intervention to individual patients.

5) ACO development, implementation and evaluation should be based on a holistic view of patient care and system-wide perspective in setting quality outcome and cost containment goals.

Payment reforms that take a narrow, more short-sighted view run the risk of managing discrete costs in the short-term at the expense of potentially increasing costs and harming quality in the

long-run. Because most payment reforms offer providers strong financial incentives to reduce costs, providers may be driven to the lowest cost treatment among treatments that are therapeutically similar for the average patient. Such reforms would fail to capture downstream efficiencies that can be realized through practice transformation and quality improvement. In some cases, a higher cost treatment may lead to better long-term patient outcomes – which are realized outside the period in which costs are counted and quality is currently measured.

To avoid harming long-term patient health, ACOs must align short-term cost incentives with metrics that evaluate longer-term outcomes. The value of a more holistic, system-wide perspective is illustrated by evaluations showing opportunities for system-wide efficiencies (e.g., reductions in unnecessary emergency room visits and hospitalizations) while preserving patient access to provider and treatment options.[2]

6) ACOs must support continued improvement in care quality – including health outcomes – and should not sacrifice quality for the sake of cost containment.

To balance cost-containment incentives, the ACO reform design must include quality measures and incentives that support continued or improved access to high quality care.

- ACOs must include robust and meaningful quality metrics that measure patient health outcomes, quality-of-life, and functional status. Process of care measures are not sufficient in payment reforms because of their extremely limited ability to identify reductions in patient access to treatment or 'stinting' on care. Consistent with this, a number of health care stakeholders and experts have called for greater reliance on outcomes-driven measures, including intermediate outcomes and patient reported outcomes, (or adequate surrogates) to help ensure the use of clinically appropriate treatment options.[3]
- ACOs should give providers meaningful incentives to improve quality. These incentives should be equal or greater to any incentives to reduce costs.
- Additional quality measures are needed to support broad payment reform. In many areas of medicine, measures have not yet been developed to enable a meaningful evaluation of, and incentives for, care quality in alternative models.[4] Stakeholders have identified significant gaps in measures of clinical and patient-reported outcomes, such as quality of life, functional status, and patient experience of care.
- Quality incentives should not conflate cost containment tools with quality measures. Performance measures or provider activities that directly relate to cost containment goals (e.g., efficiency measures or incentives for pathway adherence) reinforce new payment models' inherent cost containment incentives and therefore should not be among the quality measures or activities used to protect patients in value-based payment models.

7) If the ACOs incorporate clinical protocols, they must be grounded in solid evidence from peer-reviewed literature.

It is vital that pathways, guidelines, and value frameworks informing payment reforms support informed physician-patient decision-making from the range of treatment options and are based on well-researched, methodologically rigorous evidence. As observational data and non-experimental research designs become increasingly common via expanded electronic databases,

there is a notable lack of agreement on what constitutes good research and solid evidence upon which to make foundational changes to the health care system. Transparency of the evidence base upon which any payment reform is designed – including the cost and quality metrics – is essential; this evidence base must be kept up to date with advances in standards of care and medical technology.

MEDICAID MANAGED CARE MODEL

If, however, policymakers select a Medicaid managed care model to reform the fee-for-service system in North Carolina, PhRMA strongly encourages the following patient protections be incorporated:

a) **Protections to assure continuity of care for beneficiaries with chronic conditions.** Require continuity of coverage for patients with ongoing medication needs to treat and manage their chronic condition. Specifically, require continued coverage for a maintenance drug prescribed within the last six months —even if the drug would otherwise be non-preferred or subject to a prior authorization requirement—for as long as the patient's physician continues to prescribe the medication.

b) **Require Medicaid PDLs and MCO formularies to be comprehensive—covering prescription drugs in all categories and classes—with additional protections for vulnerable populations.** Assure or preserve additional protections for vulnerable populations. Managed care plans should cover all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes, or at least those classes that are currently carved out of the state's Medicaid preferred drug list. Similar standards apply to Medicare Part D plans.[5]

c) **Require managed care plans' formularies to be developed and reviewed by an independent pharmacy and therapeutics committee (P&T).** A majority of the members of the P&T committee should be practicing physicians, practicing pharmacists, or both, who are licensed in the state.[v] Standards should assure that P&T committee members come from various clinical specialties that adequately represent the needs of plans beneficiaries, including an adequate number of high-volume specialists, and that specialists with expertise in a specific therapeutic area participate in formulary decisions regarding each therapeutic area. Moreover, P&T committees should meet on a regular basis (not less frequently than a quarterly basis) and have a transparent process for formulary development.[v] The P&T Committee should base its clinical decisions on the strength of scientific evidence, standards of practice,[v] and nationally accepted treatment guidelines.

d) **Allow patient choice of MCO and formulary**. Patients should be allowed to select the MCO and formulary that best suits their medical needs. All plans and their formularies must be made publicly available to patients, including being posted on the plan website, in a timely manner so that patients can make appropriate healthcare decisions.

e) **Require that Medicaid MCO formularies are no more restrictive than the coverage provided under Medicaid fee for service.** In fee-for-service Medicaid, states typically use preferred drug lists (that include drugs available to beneficiaries without the need for prior authorization) to manage drug costs while providing appropriate mechanisms to obtain coverage for non-preferred/non-formulary drugs when the physician believes it's

medically necessary. In moving drug coverage to managed care, states should require managed care plans to provide coverage that is no more restrictive than the state's preferred drug list in terms of access to covered drugs.

f) **P&T committees must review medical/formulary management tools for medical appropriateness.** Specifically, the P&T committee must review the formulary management activities, such as prior authorization, step therapy, quantity limitations, generic substitutions, and other drug utilization activities for clinically appropriateness.[6]

g) **Medical management tools (e.g. prior authorization, step therapy, quantity limits) must be consistent with "best practices."** Use of medical/formulary management tools should be based on industry standards as well as appropriate guidelines from expert patient and provider organizations,[7] including that a plan must provide response within 24 hours of a request for prior authorization or override of other medical management tools.

h) **Streamlined procedures for prior authorization and other formulary management tools.** States should establish a uniform form for plans to provide physicians seeking authorization for a covered drug, including a uniform, streamlined process for handling requests for expedited review for urgent or medical emergencies. The Affordable Care Act requires the creation of a uniform exceptions and appeals process for Part D plans.

i) **Standards for exceptions and appeals.** Managed care plans must have a fair process for handling exceptions and appeals, including expedited review (within 72 hours) for urgent or emergency medical conditions as well as continued benefits during the appeal. The exceptions and appeals process shall be transparent and made publicly available to plan members as well as posted on the plan website.

j) **Review and inclusion of new prescription drugs and other treatments and therapies.** The managed care plan will cover a newly approved FDA-approved drug until such time as the plan's P&T committee has reviewed the drug for formulary inclusion.

k) **Quality and access report.** Require the state to prepare a report assessing beneficiary access no later than 18 months after the implementation of the managed care expansion to new populations and/or for new items and services. The study should assess the impact of managed care on patient access to care, and any new barriers to use of services, including prescription drugs, created by the use of medical management or cost containment tools. The report should analyze the impact on utilization of services, quality of care, and patient outcomes. The report should closely examine use of prior authorization and other plan management tools and assess whether these tools pose an undue administrative burden for physicians and/or create barriers to needed care. The report should be submitted to the state legislature, be posted on the state Medicaid website, and the agency should provide an opportunity for public comment.

In conclusion, North Carolina's Medicaid reform proposal should not miss the opportunity to improve the quality of patient care while reducing overall healthcare costs; however this potential rests on careful development and implementation. By developing a clear process which engages a broad range of stakeholders, PhRMA urges the Committee members to incorporate patient protections articulated above. PhRMA appreciates the opportunity to provide input into the Medicaid Reform work of the legislative committee and looks forward to working closely

together on developing a solution that will meet the Committee's goals without undermining patient access, quality of care and development of beneficial new treatments.

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[1] See, for example: Quintiles Outcome. Prepared for: Agency for Healthcare Research and Quality. *Developing a Protocol for Observational Comparative Effectiveness: A Users Guide.* Chapter 3: Estimation and Reporting of Treatment Effects. January 2013.

[2] See, for example, Eagle, MD, David and John Sprandio, MD. "A Care Model for the Future: the Oncology Medical Home," *Oncology.* June 13, 2011 http://www.cancernetwork.com/practice-policy/care-model-future-oncology-medical-home

[3] MedPAC. "Report to Congress, Medicare and the Health Care Delivery System." June 2013. http://www.medpac.gov/chapters/Jun13_Ch03.pdf accessed July 2014.

[4] See, for example, Table 3.3 in E.C. Schneider et al. *Payment Reform: Analysis of Models and Performance Measurement Implications.* RAND Health, 2011.

[5] Social Security Act (SSA) Section 1860D-4(b)(3)(G)

[6] 42 C.F.R. 423.120(b); Medicare Part D Manual: Chapter 6- Part D Drugs and Formulary Requirements. 30.1 Pharmacy and Therapeutics (P&T) Committee.

[7] Medicare Part D Manual: Chapter 6—Part D Drugs and Formulary Requirements. 30.2.2 Formulary Benefit Management Tools.