

April 11, 2012

Duals Project Team  
P.O. Box 45600  
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**VIA ELECTRONIC SUBMISSION**

**Re: State Demonstration to Integrate Care for Medicare-Medicaid Enrollees: Proposal to the Center for Medicare and Medicaid Innovation**

Dear Duals Project Team:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) appreciates the opportunity to submit comments regarding the Washington State Demonstration to Integrate Care for Medicare-Medicaid Enrollees.<sup>1</sup> PhRMA is a voluntary nonprofit organization representing the country’s leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA supports efforts to integrate “the delivery and financing of medical, behavioral health and long term services and supports for the Medicare/Medicaid dual eligible population” to ensure that for these individuals, the right care is provided for the right person and at the right time.<sup>2</sup> Uniquely, the State offers three strategies including: (1) Provide health homes for high cost/high risk dual-eligibles paid under the managed fee-for-service model described by the Centers for Medicare and Medicaid Services (“CMS”) (“Strategy 1”), (2) Provide fully integrated service delivery in selected counties through qualified health plans paid under CMS’ capitated financial alignment model (“Strategy 2”), and (3) Modernize the current health care delivery system to provide integrated care through health plans and use partial capitation and partial fee-for-service payments to provide strong incentives to improve the quality of care (“Strategy 3”). We appreciate the State’s clear recognition of the significant and complex health care needs of this vulnerable population, as evidenced by the State’s thorough analysis of the chronic conditions and other risk factors for its elder and non-elder dual eligible populations and the corresponding service needs for those groups.<sup>3</sup> We likewise appreciate that the State recognizes the potential damaging impact the transition to integrated care may have upon

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<sup>1</sup> Pathways to Health: Medicare and Medicaid Integration in Washington State (Mar. 12, 2012), (hereinafter “Washington Proposal”), available at <http://www.aasa.dshs.wa.gov/duals>.

<sup>2</sup> *Id.* at 5, 8.

<sup>3</sup> *Id.* at 12–15.

continuity of care for this population and commend the State's efforts to ease the transition by initially implementing fully integrated capitated health plans only in certain counties in 2013 and subsequently phasing in managed care in other counties or for individuals that opt out of full capitation integrated health plans in 2014.<sup>4</sup> We are nevertheless concerned that beneficiaries' prescription drug coverage may be inadvertently, but significantly, disrupted if the demonstration is implemented as proposed.

In particular, we urge Washington to revise its proposal to:

- Ensure that beneficiaries who enroll in Strategy 1 to receive health homes remain enrolled in their Medicare Part D plans so that the continuity of their coverage is not disrupted;
- Require plans offering integrated care through Strategy 2 and Strategy 3 to become a Medicare Part D plan or to contract with a Part D plan in order to provide the prescription drug benefit, thus ensuring that Washington residents continue to have the full range of benefits and protections currently available through Part D;
- Significantly reduce planned enrollment in the demonstration to avoid destabilizing Part D for non-dual beneficiaries and risking significant disruptions of care for beneficiaries in Washington, as well as to be consistent with the experimental nature of this initiative and allow for appropriate evaluation; and
- Reduce disruptions in care by 1) facilitating transfer of appropriate medical management and utilization history from a patient's prior Medicare Advantage or Part D plan to avoid unwarranted repetition of utilization management protocols, such as prior authorization or step therapy, simply as a result of change in coverage, and 2) establishing a transition period of at least six months during which beneficiaries can access their current providers and maintain their current prescriptions.

### **The Demonstration Must Incorporate Medicare Part D's Beneficiary Protections**

Although the proposal provides considerable statistics on the pharmacy utilization of this population, and interprets this utilization as evidence of underlying medical needs, there is no discussion of how patients' access to prescription care will be accomplished in any of the three Strategies. Since 2006, the Medicare Part D prescription drug program has effectively provided access to robust prescription drug coverage for Medicare beneficiaries, with high levels of beneficiary satisfaction, and at far lower costs than initially projected.<sup>5</sup> It has also resulted in substantial savings for other parts of the Medicare program. A recent study published by the Journal of the American Medical Association ("JAMA") found annual savings of \$1,200 on other, non-drug Medicare costs for seniors who previously had no drug coverage or limited drug coverage prior to the creation of Medicare Part D.<sup>6</sup>

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<sup>4</sup> *Id.* at 20–23.

<sup>5</sup> Congressional Budget Office, Updated Budget Projections: Fiscal Years 2012 to 2022 (Mar. 2012), at p.9, available at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/March2012Baseline.pdf>; see also Centers for Medicare and Medicaid ("CMS"), Press Release, Medicare Prescription Drug Premiums Will Not Increase, More Seniors Receiving Free Preventive Care, Discounts in the Donut Hole (Aug. 4, 2011); CMS, Press Release, Premiums for Medicare Prescription Drug Plans to Remain Low in 2011 (Aug. 18, 2010); 2004 Medicare Trustees Report, p. 164.

<sup>6</sup> J.M. McWilliams, et al., Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage, Journal of the American Medical Association (July 27, 2011).

CMS has indicated that all plans participating in the demonstration should meet Part D requirements in its *Letter to Organizations Interested in Offering Capitated Financial Alignment Demonstration Plans in Interested States* issued to plans on January 25, 2012 (the "CMS Duals Guidance"), and CMS reiterated that plans must meet these standards in *Additional Guidance on the Medicare Plan Selection Process for Organizations Interested in Offering Capitated Financial Alignment Demonstration Plans in 2013* issued to plans on March 29, 2012 (the "March CMS Duals Guidance"). While the Washington proposal mentions that the coordination initiative will incorporate Part D services, it does not provide detail about how Part D coverage will be provided under any of the strategies, and does not state explicitly that Washington intends to require health plans participating under either of those strategies to comply with the standards in the CMS Duals Guidance. We strongly urge Washington to clarify its proposal before it is submitted to CMS to expressly address its approach to Part D benefits and specifically, to confirm that prescription drug coverage will be provided consistent with the principles articulated by CMS. We believe that, consistent with the CMS Duals Guidance, a demonstration that directly incorporates Part D requirements will be more successful at maintaining beneficiary protections.<sup>7</sup> Washington can meet the requirements in the CMS Guidance by doing one of the following:

- Requiring health plans participating in Strategy 2 or Strategy 3 to be Part D plans, which would further Washington's objective of establishing "a single point of accountability over all services and supports,"<sup>8</sup> or
- Requiring such health plans to contract with Part D plans in Washington, which CMS will permit as acceptable subcontracting in the dual eligible demonstration.

The options listed above would provide pharmacy benefits through Part D plans and would ensure the maintenance of Part D protections in the demonstration, while taking advantage of cost savings and efficiencies that Part D has already created. Furthermore, these approaches are consistent with the State's demonstrated commitment to build on its past experience providing comprehensive, coordinated care to Medicare and Medicaid enrollees with complex health care needs<sup>9</sup> and with CMS' expectation that states will work with entities "that have experience in coordinating and delivering care to Medicare-Medicaid enrollees."<sup>10</sup> In addition, for those beneficiaries enrolled in Strategy 1, Washington should make clear that those beneficiaries may remain in their current Part D plans (or be allowed to switch to a new Part D plan as part of the open enrollment process).

Moreover, it is critical that Medicare beneficiaries in Washington continue to receive pharmacy benefits through Part D plans, so that rebates and discounts between drug manufacturers and Part D plans are exempted from the best price provisions of the Medicaid drug rebate statute.<sup>11</sup> Under federal law, the rebates between manufacturers and Part D plans and MA-PD plans are exempted from the best price calculation and the policies behind that exemption should be continued.<sup>12</sup> In addition, clear rules are required to assure that participating plans maintain prescription drug claims data for the dual eligible beneficiaries separate from other drug claims. Outpatient prescription drugs are a Medicare-covered benefit for dual eligible beneficiaries and may not be paid for by Medicaid.<sup>13</sup> It is therefore important that health plans

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<sup>7</sup> History has already shown that Part D can be integrated in coordinated care programs serving this population; Medicare Special Needs Plans ("SNPs") and the Program of All-Inclusive Care for the Elderly ("PACE") have successfully administered part D benefits since 2006.

<sup>8</sup> Washington Proposal at 20.

providing integrated care pursuant to Strategies 2 and 3 reflect that requirement in their operations and record-keeping, by maintaining Medicare Part D claims data and other records on dual eligible drug utilization separately from data for other lines of business, such as Medicaid managed care.

**Washington Should Limit Enrollment in the Demonstration to Avoid Significant Disruptions in Care and Destabilizing the Operation of Part D for Non-Dual Beneficiaries**

Even if Washington more fully articulates its intention to be consistent with the principles laid out by CMS, PhRMA strongly urges the State to consider the scale of the proposed Washington initiative, which raises significant risks to continuity of care and to the stability of Part D coverage available to beneficiaries who remain enrolled in traditional fee-for-service coverage. Washington reports that there are approximately 115,000 individuals who qualify for full Medicare and Medicaid benefits in the state.<sup>14</sup> Although Washington has proposed a more gradual transition to “modernized and consolidated service delivery,” the proposal appears to contemplate that over the next few years most dual eligible beneficiaries will be removed from their current Medicare Part D coverage and instead receive drug benefits through health plans that participate in Strategy 2 or Strategy 3.<sup>15</sup> Such large-scale changes in coverage create the potential for significant disruptions in patient care and could significantly alter the market dynamics in Part D. Furthermore, enrollment of the overwhelming majority of dual eligibles in the state is completely inconsistent with the experimental nature of a demonstration.

Although it is not entirely clear from the proposal, it appears that Strategy 2 envisions that the Medicaid managed care contractors that have been selected to serve Medicaid and the Washington Basic Health Plan enrollees will be the predominant plans available to duals. If essentially all of Washington dual eligibles are removed from their current Part D coverage, even if those demonstration plans were to meet all Part D requirements, the Part D program may be fundamentally altered for other non-dual eligible Medicare beneficiaries in the State because the dual eligibles will have been removed from the competitive Part D bidding system. It is critical that Washington’s demonstrations do not undermine and destabilize the prescription drug coverage that is working for non-dual Medicare beneficiaries. Indeed, Washington has noted in its proposal that one of the key concerns expressed by stakeholders, especially by beneficiaries, during the development of the proposal is that “what is working will be broken.”<sup>16</sup> Medicare beneficiaries in Washington must continue to have access to robust and affordable prescription drug benefits through Part D.

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<sup>9</sup> *Id.* at 11, 28–29.

<sup>10</sup> CMS Duals Guidance at 5.

<sup>11</sup> Social Security Act § 1927 (c)(1)(C)(i)(VI), 42 U.S.C. § 1396r-8(c)(1)(C)(i)(VI).

<sup>12</sup> See, e.g., H. Rep. 107-539, at p. 110; H. Rep. 108-178 (11), at pp. 145–46; H.R. Rep. 108-178(ii), at pp. 154–55.

<sup>13</sup> Social Security Act § 1935(d), 42 U.S.C. § 1396u-5(d).

<sup>14</sup> Washington Proposal at 7.

<sup>15</sup> *Id.* at 34–36 (noting shortcomings with Strategies 1 and 2 and emphasizing that Strategy 3 overcomes the limitations of the other two strategies).

<sup>16</sup> *Id.* at 30.

### **Washington Should Structure the Demonstration to Allow for Appropriate Evaluation**

We strongly recommend that Washington revise its proposal to reflect the experimental nature of a demonstration by limiting enrollment to a small proportion of dual eligibles in the state. Limiting enrollment to a smaller group of eligible beneficiaries is critical to protect continuity of care, assure beneficiaries access to the full protections of Part D, and to assure that such unprecedented changes in coverage can be appropriately tested and evaluated in what is truly a demonstration setting. Absent such a limitation on enrollment, it would appear that Washington is proposing to make permanent programmatic changes to beneficiaries' coverage—on a massive scale—without prior evidence from a demonstration that could assure policymakers that the proposed changes will adequately protect beneficiaries or produce savings.

Demonstrations are necessary to provide meaningful insight into the best ways to integrate care for dual eligibles, given how few health plans have experience in truly integrating care for this population. The size and scale of the Washington proposal, however, means that it does not qualify as a demonstration in any meaningful sense and will make it almost impossible to assess results in a rigorous way. Indeed, while the State proposal appears to recognize the need for evaluation and describes how the demonstration will be evaluated using control groups,<sup>17</sup> enrolling all or almost all dual eligibles into the demonstration would seem to confound such comparisons.

### **Enrollees Should Have Access to Existing Providers and Prior Authorized Drugs for at Least Six Months**

Transferring accountability on a massive scale to health plans, no matter how carefully planned, always presents risks for disrupting established patient-provider relationships and current treatment plans. Continuity of care could be lost, and patients may receive medically inappropriate substitutions of medications, or cease medication compliance altogether, if coverage is changed at the time they are seeking refills of medication, or if robust drug coverage is no longer available. We applaud Washington's proposal for creating an extensive communication campaign to educate beneficiaries about their ability to choose fully integrated care or to opt-out,<sup>18</sup> as it will help reduce the number of beneficiaries who are simply passively enrolled in integrated care and who may experience unexpected provider or plan changes as a result. However, a 90-day lock-in for those beneficiaries who fail to opt out may create health access problems. We recommend that Washington *require* the following protections for dual eligibles:

- Provide a 180-day period during which enrollees may continue to receive care from out-of-network providers, regardless of whether they have completed the screening and assessment process or whether they are undergoing active treatment for a specific condition; and
- Provide the opportunity for out-of-network providers to sign Single Case Agreements to permit them to continue to treat enrolled dual eligibles, regardless of whether the patient is undergoing active treatment for a specific condition; and

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<sup>17</sup> Washington Proposal at 39.

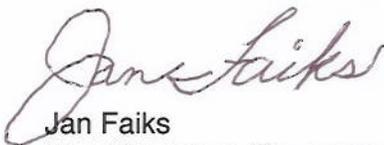
<sup>18</sup> Washington Proposal Appendices C & D.

- Provide similar transition protections regarding medications for 180 days to allow for time to make appropriate changes in medication or to apply for a new formulary exception during this period; and
- Allow beneficiaries to fill prescriptions for currently prescribed medications regardless of whether the medicine is on the formulary—current medicines should be exempted from new utilization management controls, e.g., prior authorization and step therapy. This will allow time for their physician(s) to evaluate the medical appropriateness of the proposed alternative in light of the patient's condition, other medications and health history; and
- Reduce disruptions in care by facilitating transfer of appropriate medical management and utilization history from a patient's prior Medicare Advantage or Part D plan to avoid unwarranted repetition of utilization management protocols such as prior authorization or step therapy simply as a result of change in coverage.

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We thank you for your consideration of these comments on the Washington Pathways to Health: Medicare and Medicaid Integration proposal. We urge Washington to revise its proposal in a manner that enhances coordinated care without either unnecessarily disrupting care for Washington's most vulnerable beneficiaries, or compromising Medicare prescription drug benefits for all Medicare beneficiaries in the State. We look forward to the opportunity to continue working with Washington in its development of this demonstration. Please contact me if you have any questions regarding these comments. Thank you again for your attention to these important issues.

Respectfully submitted,



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