

March 5, 2018



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VIA ELECTRONIC DELIVERY TO – <https://www.regulations.gov> “Docket Number CMS-2017-0163”

**Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter**

Dear Mr. Kouzoukas and Ms. Lazio:

GlaxoSmithKline (GSK) welcomes the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter. GSK is a science-led global healthcare company with a mission to help people do more, feel better, live longer. We have three world-leading businesses that research, develop and manufacture innovative pharmaceutical medicines, vaccines and consumer healthcare products.

Below is a summary of GSK's comments on the 2019 Advance Notice and draft Call Letter.

- **CMS – Hierarchical Condition Category (HCC) Risk Adjustment Model for CY 2019**
  - GSK recommends that CMS align risk adjustment payments to the actual cost of providing care to beneficiaries with chronic disease, such as those with chronic obstructive pulmonary disease (COPD). This can be accomplished by ensuring that COPD diagnoses are properly captured through not only diagnosis coding but by looking at the utilization of services and drugs connected to COPD. Such changes would ensure that Medicare risk scores accurately reflect the costs of beneficiaries with COPD.
- **Enhancements to the 2019 Star Ratings and Future Measurement Concepts**
  - **Display Measures being Retired:**
    - *Asthma Medication Ratio (Part C):* GSK disagrees with the decision to discontinue reporting this measure for the Medicare population and would appreciate transparency on the rationale for removing the Medicare population from this asthma-related measure since no clarity has been provided by National Committee for Quality Assurance (NCQA) in either of its Healthcare Effectiveness Data and Information Set (HEDIS) 2018 or 2019 public comment solicitations.
  - **Forecasting to 2020 and Beyond:**
    - **Potential Changes to Existing Measures:**

- *Telehealth and Remote Access Technologies (Part C) - Use of Spirometry Testing in the Assessment and Diagnosis of COPD:* GSK supports the use of telehealth and remote access technologies to replace in-person encounters for this measure, and recommends the use of patient education, an integrated care plan and other resources to improve the quality of life measures in COPD patients.
- **Potential New Measures for 2020 and Beyond:**
  - *Adult Immunization Status Composite Measure:* GSK applauds CMS on elevating the importance of rates of adult immunization using quality measures and is aligned with the goal of the National Adult Immunization Plan to strengthen the adult immunization infrastructure to support quality measure reporting.
- **Measurement & Methodological Enhancements:**
  - *Alignment Across Public Programs:* GSK recommends comparable measure alignment across Medicare quality programs. Specifically, it is important to align the clinical quality measures that are collected, reported and used for payment adjustments for plans and providers. This alignment has been started across public and private payers for incentives, infrastructure and measures.
  - *Adopt New COPD Measure Concepts into MA Star Ratings:* GSK recommends that the MA Star Ratings program increase its prioritization of COPD to align with a newly released COPD National Action Plan that seeks to greatly improve the prevention, diagnosis and treatment of the disease through the development and use of quality measures.<sup>1</sup> As CMS evolves the MA Star Ratings quality program to better capture the patient's experience with care, GSK encourages CMS to include patient-reported outcome-performance measures.
  - *Adopt Pharmacy Quality Alliance (PQA) and Health Resources and Services Administration (HRSA)-Owned, Human Immunodeficiency Virus (HIV) Core Measures:* GSK highly recommends the inclusion of PQA's Adherence to Antiretroviral Medications – Proportions of Days Covered (PDC) measure; and the HRSA/HIV Acquired Immune Deficiency Syndrome (AIDS) Bureau-owned HIV quality measures: Prescription of HIV Antiretroviral Therapy, HIV Medical Visit Frequency and HIV Viral Suppression in the MA Star Ratings since it presents an opportunity for the expanded use of HIV quality measures across public quality programs and to promote evidence-based care for HIV patients aging into Medicare.
- **Improving Access to Part D Vaccines:** GSK commends CMS for encouraging Part D sponsors to offer a \$0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing. GSK encourages CMS to take proactive steps to reduce the financial burden of vaccines for beneficiaries through the addition of the newly-developed NCQA Adult Immunization composite quality measure for the MA Star Ratings program, and consider innovative and collaborative demonstration models to address financial and other access barriers. CMS should also support an education platform aimed at increasing beneficiary and provider information and awareness about Advisory Committee on Immunization Practices (ACIP) recommended adult vaccines, vaccine coverage and the most efficient ways to access vaccines.

GSK's detailed comments on specific provisions in the Advanced Notice and draft Call Letter are provided below in the order that the issues appear in the draft document.

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<sup>1</sup> Kiley et al. "COPD National Action Plan." Chest. 152(4): 698 – 699.

## **Attachment II. Changes in the Part C Payment Methodology for CY 2019**

### **Section H. CMS-HCC Risk Adjustment Model for CY 2019: Page 30**

#### **GSK Comment:**

Ensuring Medicare Risk Score Accuracy for the Coverage of Beneficiaries with Chronic Obstructive Pulmonary Disease (COPD):

GSK appreciates the attention CMS provides to continuously improve the Medicare Advantage and Part D programs. One of the ways this can be achieved is to ensure that patients with chronic illness have access to quality treatments and care. However, the current Medicare risk adjustment program does not adequately acknowledge the amount of care and attention required to treat a beneficiary with COPD. In addition, the current methodology does not fully capture the number of beneficiaries who suffer from this condition. We recommend that CMS further evaluate the accuracy of risk adjusted payments for beneficiaries with COPD to ensure that plan payments fully reflect the cost of care. Further, we recommend that CMS incorporate prescription drug utilization into the risk adjustment program to better identify and compensate plans for beneficiaries with COPD and other chronic illnesses that can be well managed on drug therapy.

#### *About COPD*

COPD remains a significant source of morbidity and mortality in the United States. The COPD Foundation reports that COPD affects an estimated 30 million people in the U.S., many of whom do not have a proper diagnosis.<sup>2,3</sup> About 6.5% of U.S. adults reported a physician diagnosis of COPD.<sup>4</sup> However, the prevalence is significantly higher among certain populations of particular importance to Medicare. For example, the prevalence of COPD for those over age 65 is nearly double that for the broader population, and dual Medicare and Medicaid eligible beneficiaries suffer from COPD at a rate 1.7 times that of non-dual eligible (17% dual vs. 10% non-dual).<sup>5</sup>

COPD is a care-intensive condition that can significantly impair quality of life if not properly treated. In 2010, COPD accounted for approximately 11 hospitalizations per 1000 Medicare FFS beneficiaries aged ≥ 65 years old, and had an age-adjusted mortality rate of approximately 144 and 454 deaths per 100,000 in the U.S. in patients 65-74 and over 75 years old, respectively.<sup>6</sup> Among the broader population, from 1999 to 2011, COPD accounted for over 10 million physician office visits, 1.5 million emergency department visits and nearly 700,000 hospitalizations annually.<sup>7</sup> Among patients who reported having COPD in a 2011 Centers for Disease Control and Prevention (CDC) analysis, 17.7% had either visited an emergency department or been admitted to a hospital for their COPD in the previous 12 months, 64.2% felt that shortness of breath impaired their quality of life, and 55.6% were

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<sup>2</sup> COPD Foundation. "COPD Statistics Across America." (2017). Accessible at <https://www.copdfoundation.org/What-is-COPD/COPD-Facts/Statistics.aspx>.

<sup>3</sup> American Lung Association. "How Serious is COPD." (Nov. 2016). Accessible at <http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/copd/learn-about-copd/how-serious-is-copd.html>.

<sup>4</sup> Ford et al. "COPD surveillance—United States, 1999–2011." (July 2013), Chest 144(1):284-305; accessible at [http://journal.chestnet.org/article/S0012-3692\(13\)60478-X/fulltext](http://journal.chestnet.org/article/S0012-3692(13)60478-X/fulltext).

<sup>5</sup> Centers for Medicare and Medicaid Services (CMS). "Chronic Conditions Among Medicare Beneficiaries." (2012). Accessible at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>.

<sup>6</sup> Ford et al., *supra* note 4.

<sup>7</sup> Ford et al., *supra* note 4.

taking at least one daily medication for their COPD.<sup>8</sup> The rates of hospital readmissions for those suffering from COPD is also higher than that of the general population.<sup>9</sup>

These higher rates of utilization and costs of care for those with COPD are key factors in why two of the top five costliest comorbidity pairings in Medicare include COPD—those with a stroke and COPD diagnosis had costs (at \$49,025 per capita) approximately five times higher than the average spending for Medicare Fee-For-Service beneficiaries.<sup>10</sup> Additionally, national medical costs for COPD are projected to increase from \$32.1 billion in 2010 to \$49.0 billion by 2020.<sup>11</sup>

### Risk Adjustment and COPD

Several studies have suggested that Medicare Advantage Organizations (MAOs) are being underpaid with respect to risk adjustment for patients with COPD. Under payments not only impact the financial viability of MAOs—considering that risk-adjusted revenue makes up over 80% of total Medicare Advantage revenue according to an analysis by Milliman<sup>12</sup>—but ultimately influence the premiums and level of coverage for Medicare beneficiaries. A 2016 Avalere Health analysis found that total underpredicted expenditures to MA plans for all members with multiple chronic conditions (like COPD) were about \$2.6 billion per year.<sup>13</sup> In the same analysis, Avalere found that the Medicare risk adjustment program under-predicted expenditures for dual/Low Income Subsidy (LIS) eligible individuals with multiple chronic conditions by \$400 million per year.<sup>14</sup> This is particularly impactful for plans as dual eligible individuals are 1.7 times more likely to have COPD than their non-dual counterparts (17% dual vs. 10% non-dual).<sup>15</sup>

While COPD is prevalent and associated with high levels of medical service utilization, providers are often not performing the required tests sufficient to support an identification of a COPD diagnosis (either by the provider, the plan sponsor or their review entity) and, as such, fail to trigger an incremental risk factor. Despite the universal recommendation for spirometry testing in the diagnosis of COPD from consensus guidelines<sup>16</sup>, it is estimated that only one-third of newly diagnosed COPD patients have spirometry performed.<sup>17</sup> This is problematic as the Hierarchical Condition Category (HCC) risk factor is only triggered when spirometry has been performed and the COPD diagnosis is documented. In an analysis by Health First, they noted that the mere performance and documentation

<sup>8</sup> Centers for Disease Control and Prevention. "Chronic Obstructive Pulmonary Disease Among Adults — United States, 2011." (Nov. 2012). Accessible at [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6146a2.htm?s\\_cid=mm6146a2\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6146a2.htm?s_cid=mm6146a2_w) (To assess the state-level prevalence of COPD among adults, the impact of COPD on their quality of life, and the use of health-care resources by those with COPD, CDC analyzed data from the 2011 Behavioral Risk Factor Surveillance System (BRFSS). Among BRFSS respondents in all 50 states, the District of Columbia (DC), and Puerto Rico, 6.3% reported having been told by a physician or other health professional that they had COPD. In addition to the screening question asked of all respondents, 21 states, DC, and Puerto Rico elected to include an optional COPD module.).

<sup>9</sup> A June 2007 Medicare Payment Advisory Commission Report to the Congress indicated that of COPD afflicted Medicare beneficiaries, 10.7% were readmitted within 15 days costing approximately \$350 million. Medicare Payment Advisory Commission June 2007: Report to the Congress: Promoting Greater Efficiency in Medicine (Chapter 5 Payment policy for inpatient readmissions) (2007). Accessible at: [http://www.medpac.gov/docs/default-source/reports/Jun07\\_Ch05.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/Jun07_Ch05.pdf?sfvrsn=0).

<sup>10</sup> The five most costly comorbidity pairings are: stroke and kidney disease (\$51,715), stroke and COPD (\$49,025), Stroke and Heart Failure (\$47,568), Stroke and Asthma (\$46,913) and COPD and Chronic Kidney Disease (\$45,011). CMS, *supra* note 5 at p. 27.

<sup>11</sup> Earl S. Ford, MD, MPH; Louise B. Murphy, PhD; Olga Khavjou, MA; Wayne H. Giles, MD, MS; James B. Holt, PhD; Janet B. Croft, PhD, Chest. 2014. doi:10.1378/chest.14-0972. Accessible at: [http://journal.chestnet.org/article/S0012-3692\(15\)30233-6/pdf](http://journal.chestnet.org/article/S0012-3692(15)30233-6/pdf).

<sup>12</sup> Milliman. "Medicare Advantage and the Encounter Data Processing System: Be prepared." (Sept. 15, 2016). Accessible at <http://us.milliman.com/insight/2016/Medicare-Advantage-and-the-Encounter-Data-Processing-System-Be-prepared/>.

<sup>13</sup> Avalere Health. "Analysis of the Accuracy of the CMS-Hierarchical Condition Category Model." (Jan. 2016). Accessible at [http://go.avalere.com/acton/attachment/12909/f-028f/1/-/-/012016\\_Avalere\\_HCC\\_WhitePaper\\_LP\\_Final.pdf](http://go.avalere.com/acton/attachment/12909/f-028f/1/-/-/012016_Avalere_HCC_WhitePaper_LP_Final.pdf).

<sup>14</sup> *Id.*

<sup>15</sup> Centers for Medicare and Medicaid Services (CMS). "Chronic Conditions Among Medicare Beneficiaries." (2012). Accessible at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>.

<sup>16</sup> Global Initiative for Chronic Obstructive Lung Disease. "GOLD 2018 Global Strategy for the Diagnosis, Management and Prevention of COPD." (2018). Accessible at [http://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov\\_WMS.pdf](http://goldcopd.org/wp-content/uploads/2017/11/GOLD-2018-v6.0-FINAL-revised-20-Nov_WMS.pdf).

<sup>17</sup> Han MK, et al. "Spirometry utilization for COPD: How do we measure up?" (2007) Chest; 132(2):403–409. Accessible at <https://jhu.pure.elsevier.com/en/publications/spirometry-utilization-for-copd-how-do-we-measure-up-4>.

of spirometry along with the indication of the presence of COPD led to a \$310 per member per month increase in capitation payment to the MAO than with just an indication of COPD alone.<sup>18</sup> While there are other mechanisms, such as the consideration of prescription drug treatments, that could help in the identification of those with COPD, the Prescription Drug Hierarchical Condition Categories (RxHCCs) and drug utilization information are not factored into the identification of diagnoses in the MA risk calculation. This makes it significantly more difficult for MAOs to ensure comprehensive and inclusive diagnoses for those with COPD are being captured and factored into their risk scores.

With CMS's initiative to transition to the Encounter Data System (EDS), where MAOs have less audit control over the identification of diagnoses, it is even more crucial that CMS develop processes to reform the way that COPD diagnoses are identified (or supplemented). CMS must look to enhance the audit processes, ensure EDS data accuracy and completeness, and diversify the data streams used when calculating risk scores to ensure the development of accurate risk profiles for those with COPD. This will help to ensure that plans are properly paid for providing coverage to beneficiaries with COPD and ensure that providing quality coverage to beneficiaries with COPD continues to be a MAO priority.

GSK respectfully urges CMS to ensure MAOs are appropriately reimbursed for the risk and utilization burden associated with covering beneficiaries with COPD, which may aid in keeping premiums affordable for all beneficiaries. Additionally, GSK recommends that CMS ensure that those with COPD are properly accounted for in the risk adjusters used in Medicare risk adjustments. One approach to resolve this challenge is to ensure that COPD diagnoses are properly captured through not only diagnosis coding but by looking at the actual utilization of services and drugs frequently connected to an identified COPD diagnosis. A holistic review such as this can be used to identify an undiagnosed beneficiary with COPD and lead to better outcomes for both patient and provider.

GSK appreciates consideration of these recommendations by CMS and looks forward to working constructively with CMS on chronic conditions, such as COPD.

#### **Attachment VI: Draft CY 2018 Call Letter: Section I – Parts C and D**

#### **Enhancements to the 2019 Star Ratings and Future Measurement Concepts**

##### **Display Measures being Retired: Page 144**

- *Asthma Medication Ratio (Part C)*

CMS proposes to discontinue displaying this measure for 2019 due to NCQA removing the Medicare population from HEDIS.

##### **GSK Comment:**

GSK disagrees with the decision to discontinue reporting this measure for the Medicare population. Its inclusion, along with the Medication Management for People with Asthma measure could close a gap in care that currently exists for the older population (65 years and older). A 2015 analysis conducted by GSK demonstrated that the Asthma Medication Ratio was a predictor of asthmatic exacerbations in patients age 65 years and older.<sup>19</sup> Asthma related quality measures are important for the 65 years and

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<sup>18</sup> Health First. "Documentation and Reimbursement: HCC Chapter 3." Accessible at <http://www.hfni.com/images/dload/Documentation%20and%20Reimbursement.pdf>.

<sup>19</sup> Stanford RS. Predictive Ability of Therapeutic Risk Factors in Older Adult Asthma Patients, GlaxoSmithKline. Data on File 2015N236368\_00.

older population since they have a lifetime asthma prevalence of 11%<sup>20</sup> and current prevalence of asthma of about 7%.<sup>21</sup>

GSK recognizes the importance of the measures and methodology used in quality programs and their ability to provide a true reflection of plan performance and beneficiary experience with care. Given our support of the inclusion of asthma quality measures for older adults, GSK would appreciate transparency on the rationale for removing the asthma-related measures from the display page, as no clarity has been provided by NCQA in either of its HEDIS 2018 or 2019 Public Comment solicitations. GSK would welcome the opportunity to gain insight regarding the potential adjustments necessary to have these measures added back to the display page and for future inclusion in the Star Ratings program.

### **Forecasting to 2020 and Beyond**

- **Annual Call Letter Process Should Continue to be Used for Enhancements to the Star Ratings Program in the Future**

#### **GSK Comment:**

GSK supports and appreciates CMS's efforts and commitment to improve the MA and Part D Star Ratings Program. In the draft Call Letter, CMS references a proposal currently under consideration that would require that new measures or measures with substantial changes in the Star Ratings MA and Part D programs go through the Federal Register rulemaking process starting with the 2021 plan year.<sup>22</sup> Given the time-intensive nature of measure development, endorsement and adoption, GSK believes that the current annual Call Letter is the most effective process for adding new measures and keeping measure sets current. GSK urges CMS to retain the flexibility to make changes through sub-regulatory action, and does not believe it is necessary to require rulemaking for measure additions or substantial measure changes. GSK appreciates the opportunities afforded by CMS to review proposed changes and additions to Star Ratings measures and provide comment. The annual Call Letter process is the best method to align and continuously improve the Star Ratings program without the need for formal rulemaking.

- **Potential Changes to Existing Measures: Page 146**

- *Telehealth and Remote Access Technologies (Part C) - Use of Spirometry Testing in the Assessment and Diagnosis of COPD:*

CMS is seeking comment on whether telehealth and/or remote access technology encounters should satisfy as eligible encounters for the relevant portion of certain measures, specifically, whether telehealth and/or remote access technology visits are equivalent to (reasonable replacements for) in-person visits for relevant clinical areas, such as spirometry testing for COPD.

#### **GSK Comment:**

GSK commends CMS on identifying telehealth and remote access technologies as a potential means of providing high quality care for patients with COPD. A 2016 study determined that it appears feasible to supplement telemedical services with COPD monitoring capabilities, such as activity monitoring and

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<sup>20</sup> Lifetime Asthma Prevalence Percents by Age, United States: National Health Interview Survey. (2014) Accessible at: <http://www.cdc.gov/asthma/nhis/2014/table2-1.htm>.

<sup>21</sup> Current Asthma Prevalence Percents by Age, United States: National Health Interview Survey. (2014) Accessible at: <http://www.cdc.gov/asthma/nhis/2014/table4-1.htm>.

<sup>22</sup> Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (February 1, 2018), Page 145.

spirometry.<sup>23</sup> GSK recommends the use of patient education resources to assist patients in properly self-administering spirometry tests. Another study demonstrated that an integrated care plan, including disease education, self-management (including patient-administered spirometry), enhanced provider communication, and remote monitoring (via phone screening) improved quality of life measures in COPD patients.<sup>24</sup> Additional strategies for capturing patient outcomes through remote access technologies, such as monitoring smart phone activity, demonstrated through modeling that patient lung-function and GOLD classification can be predicted. GSK supports the use of telehealth and remote access technologies to replace in-person encounters for this measure.

- **Potential New Measures for 2020 and Beyond: Page 150**
  - *Adult Immunization Status Composite Measure*

CMS is seeking input on the feasibility and burden/reduction-in-burden in the collection of adult immunization measures calculated using electronic data, such as administrative claims, electronic medical records, case management systems and registries.

**GSK Comment:**

GSK applauds CMS on elevating the importance of increasing adult immunization rates using quality measures. We agree that strengthening the adult immunization infrastructure to support quality measures reporting has been identified as the first goal of the National Adult Immunization Plan.<sup>25,26</sup> NCQA demonstrated through its field-testing of the Adult Immunization Status Composite measure that not only can health plans collect and report on electronic clinical data sets (ECDS) across commercial, Medicaid and Medicare product lines, but that rates were higher in plans that used data from multiple electronic data sources, compared to only claims data.<sup>27</sup> GSK supports the decision to include this measure as a display measure and eventually as a Star Rating measure.

**Measurement & Methodological Enhancements: Page 156**

GSK appreciates the opportunity to provide suggestions to the future iterations of the Medicare Advantage (MA) Star Ratings program.

**GSK Comment:**

*Alignment Across Public Programs:*

Given the on-going need for appropriate and meaningful quality measures that address outcomes and efficient care, as the changes in service delivery and payment continue, measurement across CMS programs will need to evolve significantly over the next several years to address these dynamics.

With the delivery system transformations across public programs, quality measurement increased in importance. Private payers, as well as the government, monitor the extent to which they are investing in high quality, cost effective services that improve the health of individuals and populations.<sup>28</sup> Although there has been some alignment across public and private payers on incentives, infrastructure and measures, there hasn't been comparable alignment across Medicare quality programs, specifically, the

<sup>23</sup> Tillis W Et al. Implementation of Activity Sensor Equipment in the Homes of Chronic Obstructive Pulmonary Disease Patients. (2017) *Telemed J E Health.* 23(11):920-929. Accessible at: <http://online.liebertpub.com/doi/10.1089/tmj.2016.0201>.

<sup>24</sup> Koff PB, Jones RH, Cashman JM, Voelkel NF, Vandivier RW. Proactive integrated care improves quality of life in patients with COPD. (2009) *Eur Respir J.* 33:1031–1038. Accessible at: <http://dx.doi.org/10.1183/09031936.00063108>.

<sup>25</sup> The National Vaccine Program Office. National Adult Immunization Plan. HHS Website. <https://www.hhs.gov/sites/default/files/nvpo/national-adult-immunization-plan/naip.pdf>. Accessed February 16, 2018.

<sup>26</sup> The National Vaccine Program Office. National Adult Immunization Plan: A Pathway to Implementation. HHS Website. <https://www.hhs.gov/sites/default/files/nvpo/national-adult-immunization-plan/naip-path-to-implementation.pdf>. Accessed February 16, 2018.

<sup>27</sup> The National Committee for Quality Assurance. Draft Document for HEDIS Public Comment. NCQA Website. <http://www.ncqa.org/Portals/0/PublicComment/HEDIS-2018/05.%20Adult%20Immunization%20Status.pdf?ver=2018-02-12-095720-750>. Accessed February 16, 2018.

<sup>28</sup> The Anthem Public Policy Institute. The "Nuts and Bolts" Behind Quality Measurement in Medicaid Managed Care. Retrieved April 6, 2017, from <http://anthempublicpolicyinstitute.com>.

clinical quality measures that are collected, reported and used for payment adjustments for plans and providers.

For example, despite their ability to improve healthcare quality and health outcomes for COPD patients, there are currently no active COPD quality measures in the MA Star Ratings program.<sup>29</sup> Conversely, there are two COPD-related quality measures available for reporting in the Merit-based Incentive Programs (MIPS): i.e. COPD: Long-Acting Inhaled Bronchodilator (NQF 0102; MIPS 052)<sup>30</sup> and COPD: Spirometry Evaluation (NQF 0091; MIPS 051)<sup>31</sup>. The lack of alignment in the quality measures selected for use across quality programs and the desired outcomes for conditions, such as COPD, may result in health plans and/or providers de-prioritizing those patient populations. Additional harmonization efforts will help ensure conditions, such as COPD, continue to be prioritized appropriately across the healthcare system.

#### *Adopt New COPD Measure Concepts into MA Star Ratings*

GSK recommends that the MA Star Ratings program increase its prioritization of COPD given that it is the third leading cause of death in the U.S. and causes serious, long-term disability.<sup>32</sup> This request aligns with a newly released COPD National Action Plan developed by the National Institutes of Health and the Centers for Disease Control and Prevention, along with the many other public and private organizations, seeking to greatly improve the prevention, diagnosis, and treatment of the disease through the development and use of quality measures.<sup>33</sup> Despite its devastating impact on the US health care system, COPD-related measures have not been substantively implemented in the MA Star Ratings program. A recent study conducted by the CDC demonstrates the significant economic and quality of life impact that COPD is taking in the U.S.<sup>34</sup> The research found that in 2010<sup>35</sup> total national medical costs attributable to COPD were estimated at \$32.1 billion and total absenteeism costs were \$3.9 billion for a total burden of COPD-attributable costs of \$36 billion. National medical costs are projected to increase from \$32.1 billion in 2010 to \$49.0 billion by 2020.<sup>36</sup>

As CMS seeks to evolve the MA Star Ratings quality program to better capture the patient's experience with care, GSK encourages CMS to include patient-reported outcome-performance measures (PRO-PMS). These measures have the potential to narrow the gap between the clinician's and patient's view of clinical outcomes and help tailor treatment plans to meet the patient's preferences and needs. Additionally, these measure constructs will help to better determine what is of value to the patient beyond patient satisfaction/experience (e.g. Consumer Assessment of Healthcare Providers & Systems (CAHPS)) and facilitate informed discussions between the patient and/or the caregiver about available treatment options and gain alignment on the path forward to increase access and adherence.

Evidence shows that the systematic use of information from PRO-PMs may lead to better communication and decision-making between doctors and patients and improves patient satisfaction

<sup>29</sup> Centers for Medicare & Medicaid Services. Medicare 2017 Part C and D Display Measure Technical Notes. Accessible at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugGenIn/Downloads/2018MeasureList.pdf>.

<sup>30</sup> Quality Measure number references: Accessible at <https://qpp.cms.gov/measures/quality>.

<sup>31</sup> Id.

<sup>32</sup> Centers for Disease Control & Prevention. "Chronic Obstructive Pulmonary Disease (COPD)." (2013 April 25).

<sup>33</sup> COPD National Action Plan. Kiley, James P. et al. CHEST, Volume 152, Issue 4, 698 - 699

<sup>34</sup> Chronic Obstructive Pulmonary Disease Among Adults — United States, 2011. November 2012. Accessible at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6146a2.htm>.

<sup>35</sup> Total and state-specific medical and absenteeism costs of chronic obstructive pulmonary disease among adults aged ≥18 years in the United States for 2010 and projections through 2020, Earl S. Ford, MD, MPH; Louise B. Murphy, PhD; Olga Khavjou, MA; Wayne H. Giles, MD, MS; James B. Holt, PhD; Janet B. Croft, PhD, Chest. 2014. doi:10.1378/chest.14-0972. Accessible at: [http://journal.chestnet.org/article/S0012-3692\(15\)30233-6/pdf](http://journal.chestnet.org/article/S0012-3692(15)30233-6/pdf).

<sup>36</sup> Id.

with care.<sup>37,38,39,40,41</sup> For most patients, there is no systematic or effective method for communicating what happens outside the clinical encounter, such as perceived needs, symptoms, response to treatment, undesirable side effects, effect on function and what matters to patients and their families.<sup>42</sup>

### *Adopt PQA and HRSA-Owned, HIV Core Measures*

Innovative advances in the treatment and prevention of HIV have played a significant role in transforming HIV from what was once considered to be a terminal illness to, in many cases, a manageable, chronic disease.<sup>43</sup> Medicare is an important source of health coverage for people living with HIV. As the size of U.S. HIV positive population has grown over time, so too have the number of Medicare beneficiaries with HIV. The number of Medicare beneficiaries with HIV have tripled since the 1990s, rising from 42,520 in 1997 to 120,000 in 2014.<sup>44,45</sup> Many Medicare beneficiaries with HIV are dually-eligible for Medicare and Medicaid, and receive low-income subsidies under Part D.<sup>46</sup> Medicare spending for HIV has also increased over time, and the program is now the single largest source of federal financing for HIV care and treatment.

Evidence-based quality measures assessing HIV care exist, are endorsed by National Quality Forum (NQF), and used in federal programs, such as the MIPS and the Ryan White HIV/AIDS Program.<sup>47,48</sup> However, the MA Star Ratings program does not address HIV. HIV quality measures are critical to elevating the importance of the care and treatment of patients living with HIV and for reducing the incidence of new HIV infections. The HIV care continuum and measurement framework of diagnosis, treatment, and viral load suppression leading to prevention is aligned with the Institute for Healthcare Improvement's Triple Aim of improving patient experience, reducing cost and improving population health.<sup>49</sup>

A 2011 interim analysis of the National Institutes of Health (NIH) HIV Prevention Trials Network study, HPTN 052 found that treating HIV-1-infected patients with antiretroviral therapy (ART) reduced the risk of transmitting the virus to HIV-negative sexual partners by 96%.<sup>50</sup> The final analysis involved over five years of follow up in the full set of HIV-1-infected partners, and found a 93% reduction in transmission

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<sup>37</sup> Chen J, Ou L, Hollis SJ. A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organizations in an oncologic setting. *BMC Health Serv Res* 2013; 13:211.

<sup>38</sup> Marshall S, Haywood K, Fitzpatrick R. Impact of patient-reported outcome measures on routine practice: a structured review. *J Eval Clin Pract* 2006; 12:559-68.

<sup>39</sup> Santana M-J, Feeny D. Framework to assess the effects of using patient-reported outcome measures in chronic care management. *Qual Life Res* 2014; 23:1505-13.

<sup>40</sup> Valderas JM, Kotzeva A, Espallargues M, Guyatt G, Ferrans CE, Halyard MD, et al. The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. *Qual Life Res* 2008; 17:179-93.

<sup>41</sup> Wasson JH, Stukel TA, Weiss JE, Hays RD, Jette AM, Nelson EC. A randomized trial of using patient self-assessment data to improve community practices. *Effect Clin Pract* 1999; 2:1-10

<sup>42</sup> Nelson Eugene C, Eftimovska Elena, Lind Cristin, Hager Andreas, Wasson John H, Lindblad Staffan et al. Patient reported outcome measures in practice *BMJ* 2015; 350: g7818

<sup>43</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Department of Health and Human Services. Accessible at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed 26 Feb 2018.

<sup>44</sup> <https://www.kff.org/hivaids/fact-sheet/medicare-and-hiv/#footnote-200104-3>.

<sup>45</sup> The 1997 estimate is from Gilden DE, Kubisiak JM, Gilden DM. Managing Medicare's HIV Caseload in the Era of Suppressive Therapy, *AJPH*. Vol. 97, No. 6; June 2007. The 2014 estimate is based on Kaiser Family Foundation's analysis.

<sup>46</sup> Kaiser Family Foundation analysis of the 5% sample (see endnote 2) and CDC. (2014) Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV — United States, 2011. *MMWR*. 63(47);1113-1117. Accessible at:

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a5.htm?s\\_cid=mm6347a5\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a5.htm?s_cid=mm6347a5_w)

<sup>47</sup> <https://www.kff.org/global-health-policy/fact-sheet/u-s-federal-funding-for-hivaids-trends-over-time/#footnote-242359-3>

<sup>47</sup> Quality Measures. Quality Payment Program. <https://qpp.cms.gov/mips/quality-measures>.

<sup>48</sup> Performance Measure Portfolio. HRSA. <https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio>. Accessed February 16, 2018.

<sup>49</sup> The IHI Triple Aim. IHI. <http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx>.

<sup>50</sup> Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011; 365:493-505. See also <http://www.cdc.gov/hiv/prevention/research/art/>;

risk.<sup>51</sup> These outcomes can only occur, however, if people living with HIV have access to medical care, are diagnosed, receive treatment and remain adherent to treatment. The use of HIV-related quality measures will promote standards of health care coverage that support adherence to current HIV clinical guidelines and federal guidelines.<sup>52</sup>

GSK highly recommends the inclusion of the following PQA and HRSA HIV/AIDS Bureau-owned, HIV quality measures:

- Adherence to Antiretroviral Medications – Proportions of Days Covered (PDC) measure
- Prescription of HIV Antiretroviral Therapy
- HIV Medical Visit Frequency
- HIV Viral Suppression

Adoption of these measures into the MA Star Ratings program presents an opportunity for the expanded use of HIV quality measures across public quality programs and to promote evidence based care for those patients aging into Medicare.

### **Section III – Part D**

#### **Improving Access to Part D Vaccines: Page 199**

In the draft CY 2019 Call Letter, CMS highlights that the Center for Disease Control and Prevention (CDC) has reported that vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap), and that approximately 70% of adults for whom the herpes zoster vaccine is recommended remain unprotected.<sup>53</sup> CMS encourages Part D sponsors to either offer a \$0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing in an effort to improve access to these and other Part D vaccines.<sup>54</sup> Also, the “Benefits and Parameters for CY2019 Threshold Values” table in the draft Call Letter provides an example of the Vaccine Tier and contains a footnote on the ability to utilize a lower cost-sharing tier for vaccines.<sup>55</sup>

#### **GSK Comment:**

GSK commends CMS for providing information on the status of vaccination rates for the adult population in the United States and for encouraging Part D sponsors to utilize available benefit parameters within Part D to offer a \$0 vaccine tier, or to place vaccines on a formulary tier with low cost-sharing.

Vaccination is one of the most important public health achievements of the past century, saving countless lives and improving the quality of life by preventing many serious infectious diseases. Prevention not only saves lives, but also helps to lower health care costs. For example, research has shown that for every \$1 the U.S. spends on childhood vaccinations, we save \$10.20 in disease treatment costs.<sup>56</sup>

Unfortunately, however, access to vaccines is not equal across a person’s lifespan. As CMS discusses in the draft Call Letter, the CDC has reported that vaccination rates remain low for tetanus and diphtheria with acellular pertussis (Tdap), and that approximately 70% of adults for whom the herpes

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<sup>51</sup>Cohen MS, Chen YQ, McCauley M, et al. Antiretroviral therapy for the prevention of HIV-1 transmission. *N Engl J Med* 2016; 375:830-839. Accessible at: <http://www.nejm.org/doi/full/10.1056/NEJMoa1600693>

<sup>52</sup> HIV Medicine Association. Tools for Monitoring HIV Care: HIV Clinical Quality Measures (Updated) February 2015. Accessible at: [http://www.hivma.org/uploadedFiles/HIVMA/Policy\\_and\\_Advocacy/Policy\\_Priorities/Increased\\_Federal\\_Funding/Comments/Tools\\_for\\_Monitoring\\_Issue\\_Brief\\_update%20Jan%202015.pdf](http://www.hivma.org/uploadedFiles/HIVMA/Policy_and_Advocacy/Policy_Priorities/Increased_Federal_Funding/Comments/Tools_for_Monitoring_Issue_Brief_update%20Jan%202015.pdf). Accessed: March 20, 2017.

<sup>53</sup> Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (February 1, 2018), Page 199.

<sup>54</sup> Id, Page 199

<sup>55</sup> Id, Pages 199 - 201.

<sup>56</sup> Zhou F et. al. Economic evaluation of the routine childhood immunization program in the United States, 2009. *Pediatrics* 2014;133(4):1-9.

zoster vaccine is recommended remain unprotected.<sup>57</sup> For example, in 2014 only 20.1% of adults 19 years and older reported having received the Tdap vaccine that helps protect against tetanus, diphtheria and pertussis (or “whooping cough”), and just 27.9% of adults 60 years and older reported receiving the vaccine for herpes zoster, or “shingles.”<sup>58</sup> These numbers are especially concerning because vaccines for these diseases are routinely recommended for adults by an independent expert advisory body to the CDC, called the Advisory Committee on Immunization (ACIP), which is charged with carefully assessing vaccine safety and benefits for patients.<sup>59</sup> Medical costs related to vaccine-preventable diseases (VPD) in older adults are high and are expected to grow substantially in the coming years; one study forecasts U.S. medical costs for Americans ≥65 in the Medicare population to be \$4.74 billion by 2030 for just one VPD.<sup>60</sup>

While there are many factors contributing to low adult immunization rates, financial barriers; such as out-of-pocket costs, stand out as one of the most impactful and avoidable barriers to prevention. Medicare beneficiaries often face some of the highest vaccine out-of-pocket costs. Vaccine coverage under Medicare is a patchwork. Medicare Part B provides first-dollar coverage for influenza and pneumococcal vaccines, as well as for Hepatitis B vaccine for diabetics and other high risk groups. All other vaccines, including Tdap and shingles vaccines, are covered under the optional Part D program, and since there are no vaccine cost-sharing requirements for Part D plans, beneficiary out-of-pocket costs are often high.

Research shows that higher beneficiary out-of-pocket costs for vaccines lead to a lower chance of vaccination. A GSK study evaluated the relationship between vaccine co-pays for Part D beneficiaries and Tdap and Zoster vaccination claims in their doctor’s office.<sup>61</sup> The results showed that, compared with no co-pay, beneficiaries who had to pay a co-pay amount of \$26–50, \$51–75 or \$76–100, respectively, are 1.39, 1.66 or 2.07 times as likely to cancel their zoster vaccination. Another recent study found that patient out-of-pocket (OOP) cost is one of the most significant predictors of vaccine abandonment, after adjusting for other factors.<sup>62</sup>

Additionally, a recently released analysis by Manatt Health Strategies reported that in 2017, only 4% of non-Low Income Subsidy (LIS) enrollees in Part D had access to vaccines without cost sharing.

Highlights of the analysis include:

- Overall, less than 9% of non-LIS MA-PDP enrollees had access to zero-cost vaccines and no non-LIS enrollees in PDPs had access to zero-cost vaccines. For non-LIS enrollees in Medicare Advantage with a Prescription Drug Plan (MA-PDP), more than 30% had a coinsurance rate greater than 35% with the median estimated out-of-pocket for non-LIS MA-PDP enrollees in 2017 between \$39 and \$47. Among MA-PDPs that require copayments in 2017, less than 3% of non-LIS enrollees had copayments less than \$26 for the vaccines in this analysis.
- No standalone Prescription Drug Plan (PDP) offered \$0 cost-sharing to non-LIS enrollees. Among PDPs that required coinsurance for non-LIS enrollees in 2017, rates were rarely less than 11% with coinsurance 35% or greater for most vaccines in the analysis. For PDPs that required copayments, less than 9% of non-LIS beneficiaries had copayments under \$26 in 2017. The overall cost-sharing

<sup>57</sup> Centers for Medicare & Medicaid Services (CMS), Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter (February 1, 2018), Page 199.

<sup>58</sup> Williams WW, Lu PJ, O’Halloran A, et al. Centers for Disease Control and Prevention (CDC). Surveillance of vaccination coverage among adult populations – United States, 2014. MMWR Surveill Summ 2016; 65:1-36.

<sup>59</sup> U.S. Centers for Disease Control and Prevention. Recommended Adult Immunization Schedule for Adults Aged 19 Years or Older, by Vaccine and Age Group, Accessible at: [http://www.vaccines.gov/who\\_and\\_when/adults/index.html](http://www.vaccines.gov/who_and_when/adults/index.html).

<sup>60</sup> Varghese L et al. The temporal impact of aging on the burden of herpes zoster. BMC Geriatrics (2017) 17:30.

<sup>61</sup> Yan S et al., Relationship between Patient Copayments in Medicare Part D and Vaccination Claim Status for Herpes Zoster and Tdap. Poster session presented at 2015 EDUCATIONAL CONFERENCE OF THE ACADEMY OF MANAGED CARE PHARMACY (AMCP NEXUS).

<sup>62</sup> Akinbosoye OE et al. Factors Associated with Zostavax Abandonment. AJPB. 2016;8(4):84-89. Accessible at: [http://www.ajpb.com/journals/ajpb/2016/AJPB\\_JulyAugust2016/factors-associated-with-zostavax-abandonment](http://www.ajpb.com/journals/ajpb/2016/AJPB_JulyAugust2016/factors-associated-with-zostavax-abandonment)

for non-LIS PDP enrollees ranged between \$27 and \$75 depending on the vaccine for 2017. The analysis noted that the estimated out-of-pocket costs could exceed \$100 for either MA-PDP or PDP non-LIS enrollees for some vaccines.<sup>63</sup>

These findings echo those from a 2016 report by Avalere Health that examined Medicare Part D plan coverage between 2011 and 2016 for 10 adult vaccines from the list of ACIP-recommended vaccines that either had age specific recommendations for seniors or conditions where seniors were the target population.<sup>64</sup> This data suggests that CMS's encouragement in the annual Call Letter alone is not sufficient to increase beneficiary access to Part D vaccines.

To move beyond simply encouraging plans, GSK urges CMS to take additional proactive steps to reduce the financial burden of vaccines for beneficiaries in the Part D program. For example, we reiterate the importance of adding the newly-developed NCQA Adult Immunization composite quality measure for the MA Star Ratings program, as this would provide a meaningful incentive for MA-PD plans to take steps to increase adult immunization rates in their beneficiary populations (see "Potential New Measures for 2020 and Beyond; *Adult Immunization Status Composite Measure*" on page 7 of this letter). In addition, we recommend that CMS consider innovative and collaborative models such as demonstrations under the Center for Medicare and Medicaid Innovation (CMMI) authority to show that lower beneficiary OOP costs for Part D vaccines will increase immunization rates, lower costs for the Medicare program, and ultimately produce better health outcomes. GSK welcomes the opportunity to progress with CMS value-based arrangements and other ideas to reduce financial barriers for patients.

Finally, while removing financial barriers would have a significant impact on improving beneficiary access to and utilization of vaccines, GSK recommends that CMS consider other important activities that could remove barriers that keep older adults from receiving ACIP-recommended vaccines.

Medicare beneficiaries are often unaware of which vaccines are recommended by ACIP and how those vaccines are covered under Medicare. Vaccine education, both before and after joining Medicare, is therefore critical to help adult patients make informed decisions about which vaccines are needed and the coverage options available to them. CMS should support an education platform aimed at increasing beneficiary and provider information and awareness about ACIP-recommended vaccines, vaccine coverage, and the most efficient ways to access them, especially under the Part D program. To build this platform, GSK recommends the following:

- **Update the Pre- Enrollment Materials to Include Information about Vaccine Coverage in Medicare** – Beneficiaries who will be eligible for Medicare receive a "Welcome to Medicare" information packet before they are enrolled, which currently includes very limited information on vaccine coverage. These materials could be updated to include language about ACIP recommended vaccine coverage and general information about Medicare coverage of vaccines under Part B and Part D.
- **Include Additional Information on Vaccine Coverage in the Medicare & You Handbook** – CMS should update the Medicare & You Handbook to include language describing ACIP recommendations on vaccines and provide information on the differences in Part B and Part D vaccine coverage. Making these changes will allow beneficiaries to have some basic information

<sup>63</sup> Manatt Health Strategies, Issue Brief with Chart Pack; "Trends in Medicare Part D Benefit Design and Cost Sharing for Adult Vaccines, 2015-2017; February 2018, Accessible at: <https://www.manatt.com/Insights/White-Papers/2018/Medicare-Part-D-Cost-Sharing-Trends-for-Adult-Vacc>). GlaxoSmithKline provided funding for this analysis. Manatt maintained full editorial control, including selection of the vaccines, methodology and content of the paper.

<sup>64</sup> Avalere Health, "Adult Vaccine Coverage in Medicare Part D Plans", February 2016. Accessible at: <http://avalere.com/expertise/managed-care/insights/medicare-has-the-potential-to-avoid-preventable-illnesses-by-encouraging-br> (accessed February 25, 2016). GlaxoSmithKline provided funding for this analysis. Avalere maintained full editorial control, including selection of the vaccines, methodology and content of the paper.

about Medicare immunization coverage as they make their decisions about Medicare Part D enrollment.

- **Ensure Providers are Engaging Medicare Beneficiaries on Immunizations in Prevention Visits** – One of the more important ways to encourage immunizations among adult beneficiaries is for providers to talk to their patients about recommended immunizations.<sup>65</sup> Currently, Medicare covers Initial Preventive Physical Examination (IPPE) for new beneficiaries during their first year in Medicare as well as an annual wellness visit (AWV) each year thereafter. These visits are important engagement opportunities for beneficiaries, especially to educate them about recommended vaccinations, discuss ways to access those vaccines, and even write prescriptions for needed vaccines.
- **Increase Part D Plan Information and Engagement** – Part D plan information can play an important role in efforts to increase immunization rates for ACIP-recommended vaccines among beneficiaries. CMS should consider improving information on vaccine coverage on Medicare Plan Finder to help beneficiaries incorporate this information into decisions about Part D plan enrollment. Further, CMS could consider requiring Part D plans to send beneficiaries vaccine reminder notices at least once a year to prompt beneficiaries to talk to their doctors about needed vaccines and detailing how the Part D plan covers vaccinations.

GSK greatly appreciates the opportunity to comment and CMS's consideration of our recommendations on the "Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and draft 2019 Call Letter." Please do not hesitate to contact me with any questions. Thank you for your attention to these important issues.

Respectfully submitted,



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GlaxoSmithKline

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<sup>65</sup> Shen, A. K., Warnock, R., & Kelman, J. A. (2017). Driving immunization through the Medicare Annual Wellness Visit: A growing opportunity. *Vaccine*. DOI: [10.1016/j.vaccine.2017.10.055](https://doi.org/10.1016/j.vaccine.2017.10.055)