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February 13, 2023

Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (Docket No.: CMS-2022-0791)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to respond to the proposed rule regarding Contract Year 2024 policy and technical changes to the Medicare Advantage (MA or Part C) and Medicare Prescription Drug Benefit (Part D) programs (hereinafter "Proposed Rule"). Vizient applauds CMS for issuing a request for information (RFI) regarding MA, to which Vizient commented in August 2022, and for the agency's decision to use such comments to inform the Proposed Rule.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient appreciates the efforts of CMS to improve beneficiaries' protections and to promote equity in coverage and care. Vizient offers the following recommendations for the agency's consideration as related to utilization management (UM), marketing and health equity.

Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and a Mandated Annual Review of Utilization Management Tools

In the Proposed Rule, CMS notes that UM tools, including prior authorization (PA), are designed to help MA plans determine the medical necessity of services. Consistent with concerns Vizient shared in our August 2022 comments, CMS acknowledges that UM in MA can create a barrier to patients accessing medically necessary care. Vizient applauds the agency for issuing the Proposed Rule as a response as it provides several requirements to help ensure appropriate use of UM tools and timely access to medically necessary care.

Basic Benefits Coverage

CMS proposes to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than traditional Medicare. As part of this effort, the agency proposes that the MA organization (MAO) cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in traditional Medicare coverage policies. Vizient is supportive of efforts to better ensure coverage provided by MAOs aligns with traditional Medicare. We emphasize that variable coverage policies, including those related to basic benefits, by MAOs add significant administrative burden and can negatively impact patient access to care. We offer several recommendations for the agency to consider or clarify to further reduce burden and support access.

Step Therapy Policies

In the Proposed Rule, CMS clarifies that it is not proposing to revise regulations which authorize an MAO's use of step therapy policies for Part B drugs. In doing so, the agency notes its comments in prior rulemaking[1] that the regulations for MA and step therapy for Part B drugs "put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing for the beneficiary." However, Vizient questions this assertion. For example, recent research found that while step therapy can direct beneficiaries to lower-cost options, in circumstances "where a similar lower-cost option is not available, coverage restrictions burden clinicians and limit access to critical medications" while beneficiaries do not benefit from reduced out-of-pocket costs.[2] In addition, it is unclear as to whether the agency has more recently studied the impact of step therapy since prior rulemaking. While current step therapy regulations are relatively new, we encourage the agency to work with stakeholders to identify various step therapy challenges and revise the regulations to help resolve such issues.

[1] Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 84 Fed. Reg. 100
[2] Anderson, K.E.., Alexander, C.G., Ma, C., Dy, S.M. & Sen, A.P. (2022). Am J Manag Care.28(7):e255-e262. https: https://doi.org/10.37765/ajmc.2022.89184, last accessed: February 3, 2023.

Access to Specialty Medications

As CMS is aware, MA plans often require that prescriptions for specialty medications are filled at specific specialty pharmacies or specialty pharmacy networks. Such policies can limit patient access to other pharmacies willing to dispense specialty medications and provide related patient-care services. These coverage frameworks also lead to fragmented care as plans are often unwilling to include other pharmacies, even if a pharmacy satisfies additional standards (e.g., accreditation). In the Proposed Rule, CMS does not address opportunities to improve patient access to specialty medications that is limited due to such restrictions or networks. Vizient encourages CMS to work with stakeholders to ensure patient access to care and medications can be improved by considering improvements to current models for specialty medications.

Payer-Mandated White Bagging

While not addressed in the Proposed Rule, Vizient suggests CMS consider the permissibility of payer-mandated “white bagging”[3] policies, as such policies effectively force patients to receive medications from a payer-identified specialty pharmacy rather than traditional buy-and-bill channels. Payer-mandated white bagging policies complicate access and care by creating delivery and dispensing delays and slowing speed to therapy for patients. Based on a Vizient survey regarding such payer-mandated policies, 92% of provider respondents experienced patient care issues due to problems with medications received through these channels, while 23% hired additional staff (ranging from 0.5 – 8 full-time employees) to manage white bagging and brown bagging.[4] Vizient believes there is a critical need for CMS to address the significant administrative burden and interruption to patient care stemming from these payer-mandated policies. We encourage the agency to clarify in the final rule that MA plans may not require white bagging, as doing so restricts access to basic benefits as compared to traditional Medicare.

Medical Necessity Determinations

In the Proposed Rule, CMS proposes various policies to support more robust individual medical necessity determinations, such as the need for plans to consider an enrollee’s medical history, physician recommendations, and clinical notes when making medical necessity determinations. However, CMS also notes that it is unable to quantify the impact of these proposed policies, as MAOs may already be interpreting current guidance in a manner

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[3] According to the National Association of Boards of Pharmacy (NABP), ‘*White and Brown Bagging Emerging Practices* (2018), available at: https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf, “White bagging” refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician’s office, hospital, or clinic for administration. It is often used in oncology practices to obtain costly injectable or infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies.

[4] According to the National Association of Boards of Pharmacy (NABP), ‘*White and Brown Bagging Emerging Practices* (2018), available at: https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf, ““Brown bagging” refers to the dispensing of a medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medication(s) to the physician’s office for administration.

consistent with the Proposed Rule. Given the frequency in which MAOs are interpreting current requirements in a way that aligns with the proposed policies, Vizient suggests CMS provide additional education to plans should this policy be finalized.

Appropriate Use of Prior Authorization

In the Proposed Rule, CMS notes that, with limited exceptions, all services covered by MA coordinated care plans may be subject to prior authorization (PA). CMS proposes that PA should only be used to confirm the presence of diagnosis or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary (or clinically appropriate for supplemental benefits) and should not function to delay or discourage care. However, Vizient notes that it is possible that PA may be used for the purposes CMS identifies, while also having the consequence of delaying or discouraging care. Vizient encourages CMS to consider working with providers to better identify circumstances in which PA policies unnecessarily delay or discourage care, particularly if other recently proposed rulemaking[5] that addresses timeliness of PA decisions is not finalized.

Continuity of Care

Among other proposed policies related to continuity of care, CMS proposes a 90-day transition period when an enrollee currently undergoing treatment switches to a new MA plan. Vizient appreciates this policy, as we agree that continuity of care becomes more challenging once coverage changes. Vizient also encourages CMS to consider communicating changes regarding such a transition policy, if finalized, to patients and providers. In addition, Vizient suggests CMS provide additional resources to support implementation for different scenarios (e.g., if an enrollee has multiple treatments and some would be covered under continuity of care requirements).

Termination of Services in Post-Acute Care

In the Proposed Rule, CMS indicates it has received complaints about potential quality of care issues regarding early termination of services in post-acute care settings by MAOs (e.g., before the beneficiary is healthy enough to return home). The agency proposes to revoke the current policy that when a health care service is covered by Medicare and delivered in more than one way, or by more than one type of practitioner, an MA plan can choose how the covered services will be provided. As proposed, the MAO may only deny coverage of the services or setting on the basis of ordered services failing to meet certain requirements.[6] Vizient supports CMS's decision to clarify this policy, as it will help optimize beneficiaries' care options. Further, we encourage the agency to ensure that beneficiaries are provided

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[5] 87 Fed. Reg. 238, available at: https://www.govinfo.gov/content/pkg/FR-2022-12-13/pdf/2022-26479.pdf.

[6] The requirements CMS references are outlined in proposed 42 CFR 422.101(c)(1)(i) which details the data in which MAOs much make medical necessity determinations.

information in the termination notice that details the rationale for the termination of services, as this may streamline appeals and potentially prevent early termination decisions.

More generally, Vizient reiterates prior concerns regarding access to post-acute care when a patient is ready for discharge from an acute care setting. Vizient's members have indicated that patients may be spending excess time in a hospital because of delays in accessing post-acute care. While this issue is not directly related to termination of post-acute care services, it is important that CMS also consider potential policies to bolster access to post-acute care so that patients may both seamlessly access post-acute care and continue to receive post-acute care services without premature termination or incentives to terminate care early. More generally, Vizient requests the agency consider increasing reimbursement for acute care providers so that longer lengths of stay due to challenges in finding post-acute care for patients are reflected in Medicare payment policy.

Gold-Carding Programs

In the Proposed Rule, CMS reiterates that it believes the use of gold-carding programs could help alleviate the burden associated with PA and that such programs could facilitate more efficient and timely delivery of health care services to enrollees. Vizient encourages CMS to work with providers and plans to consider sharing best practices related to gold-carding programs to broaden their use and provider participation.

MA and Part D Marketing

In the Proposed Rule, CMS provides numerous changes to regulations around MA and Part D marketing to protect Medicare beneficiaries. Among other changes, CMS proposes regulations for third-party marketing organizations (TPMOs) operating on behalf of MA and Part D plans and policies related to potentially misleading advertising. Generally, Vizient applauds CMS for these proposals. We encourage the agency to continue to listen to stakeholders, including providers and patients, to ensure compliance should the Proposed Rule be finalized.

Health Equity Index (HEI) Reward

While Vizient's primary focus has typically been hospitals and providers, we appreciate the agency's efforts to consider the role of MA and Part D plans in addressing health inequities. CMS proposes to replace the current reward framework with an HEI reward for the 2027 Star Ratings. CMS indicates that the proposed HEI reward aims to encourage high and stable performance across various quality measures in underserved populations. Although Vizient is supportive of the agency's goal to improve health equity, we offer various insights for consideration regarding the HEI reward.

Purpose of the Health Equity Index

CMS states its intention to address health equity through the development of the HEI reward, which it believes will incentivize plans to address health disparities in their membership. However, based on the proposal, it is unclear to Vizient if CMS is proposing a methodological

change to the way the star ratings are calculated, or if it is creating a new patient-level index that could have broader use in the context of health equity. Further, CMS states that it is not using the Area Deprivation Index (ADI) because the ADI did not provide more meaningful data than the low-income subsidy/dual eligible (LIS/DE) and disability analysis. The proposed HEI reward relies on patient-level data but does not capture several other social risk factors (SRFs) or social determinants of health (SDOHs), such as food insecurity or housing instability, which are apparent at the neighborhood level. While Vizient agrees that the ADI does not accurately capture many of the factors important for the purposes of achieving health equity, we ask that the agency clarify which social ecological levels (*see* Figure 1) the HEI reward is meant to include so that we may provide additional feedback.

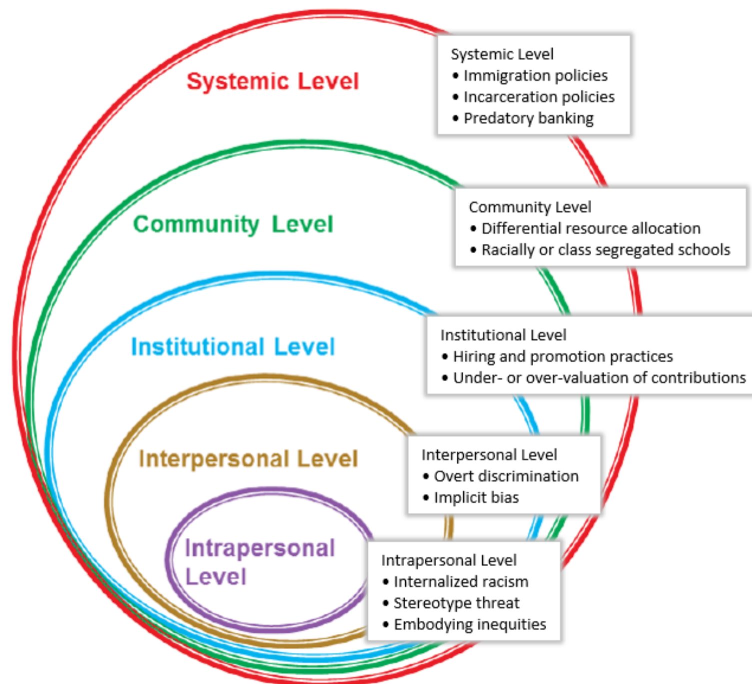

Figure 1. Social ecological model[7] that may be useful to CMS as health equity approaches are considered.

Use of Neighborhood-Level Indices

Although Vizient agrees with CMS that the ADI does not provide sufficiently meaningful data to help address health inequities, we believe this should not preclude CMS from considering other neighborhood-level indices in future policy that aim to address health inequities. Vizient developed the Vizient Vulnerability Index™ (VVI™) (*see* Appendix 1 for more information) specifically to address health disparities. We believe the VVI™ could potentially be utilized for the purposes of the HEI reward. Vizient welcomes the opportunity to discuss this option with CMS.

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[7] *See* National Academies of Sciences, Engineering, and Medicine 2017. Communities in Action: Pathways to Health Equity. Washington, DC: The National Academies Press. https://doi.org/10.17226/2462, sourcing, a concept from McLeroy, K. R., D. Bibeau, A. Steckler, and K. Glanz. 1988. An ecological perspective on health promotion programs. Health Education Quarterly 15:351–377.

Terminology

CMS proposes that the HEI reward would reflect contract performance among those with certain SRFs (i.e., those who receive a low-income subsidy or are dually eligible or have a disability) and that additional SRFs may be added in the future. The proposed HEI reward would boost a plan's Star Rating if it obtains high measure-level scores for the subset of enrollees with the specified SRFs. Vizient is concerned that the term "Health Equity Index" might be confusing to stakeholders, as various indices have been addressed in other CMS programs (e.g., Medicare Shared Savings Program, ACO REACH) and may not reflect CMS's apparent intention of only using the HEI to make a methodological change to MA and Part D Star Ratings. Should CMS decide to implement an HEI reward, we encourage CMS to clarify that the HEI reward is being used solely as a methodological change and to use terminology other than "Health Equity Index" to prevent confusion.

Proposed SRFs for Inclusion in the HEI Reward

As proposed, a limited number of SRFs are included (e.g., LIS/DE and having a disability) in the HEI and it is unclear how CMS decided to prioritize these SRFs or if other SRFs can be considered. In addition, the SRFs proposed include LIS/DE and disability, all of which can be extracted from a Medicare beneficiary's enrollment. Because of the method in which CMS collects the proposed SRFs, it is unclear how CMS envisions expanding the HEI in the future. For example, will the agency consider other data sources? While these SRFs are important and relevant to a beneficiary's outcomes, Vizient encourages CMS to consider using other SRFs or SDOH, such as transportation or food insecurity, that plans may be better positioned to address. For example, it may be challenging to identify specific drivers of health inequities if only the proposed SRFs are known. To better encourage plans to consider drivers of health inequities, Vizient urges CMS to adjust the HEI reward to include other SRFs and SDOH that plans can more meaningfully address through their benefits. As CMS may receive comments regarding additional SRFs, we suggest the agency carefully consider which factors are within a plan's locus of control.

Also, CMS states in the Proposed Rule that it intends to include other factors in the HEI reward through future rulemaking. However, other factors, such as food insecurity, housing instability, or lack of access to transportation, are not included in enrollment, and would require additional data. As noted above, it is unclear to Vizient how CMS would access data or how it would be shared. Collecting this data would require standards for consistency and additional time to speak with beneficiaries. While Vizient appreciates the agency's efforts to rely on patient collected enrollment data, we are concerned that the patient collected data on other SRFs or SDOH is not currently available to develop an HEI reward that more directly encourages plans to address drivers of health inequities. As a short-term measure, Vizient encourages CMS to explore other indices that reflect SDOH, particularly the VVI™, which already incorporates eight SDOH domains, was designed to help support health equity and fits well to life expectancy across the country. The VVI™ and other neighborhood-level indices also reflect these SDOH domains which can help inform approaches to address inequities, unlike the few SRFs CMS has identified. For example, Figure 2 demonstrates substantial regional differences in SDOH domain vulnerabilities using the VVI™. Vizient believes such a shift would help

encourage plans to address specific SDOH if included in the HEI reward. As such, Vizient recommends CMS use the VVI™ or other appropriate area-based indicators with patient-level address and/or zip code as a short-term measure until more detailed patient-specific data is collected.

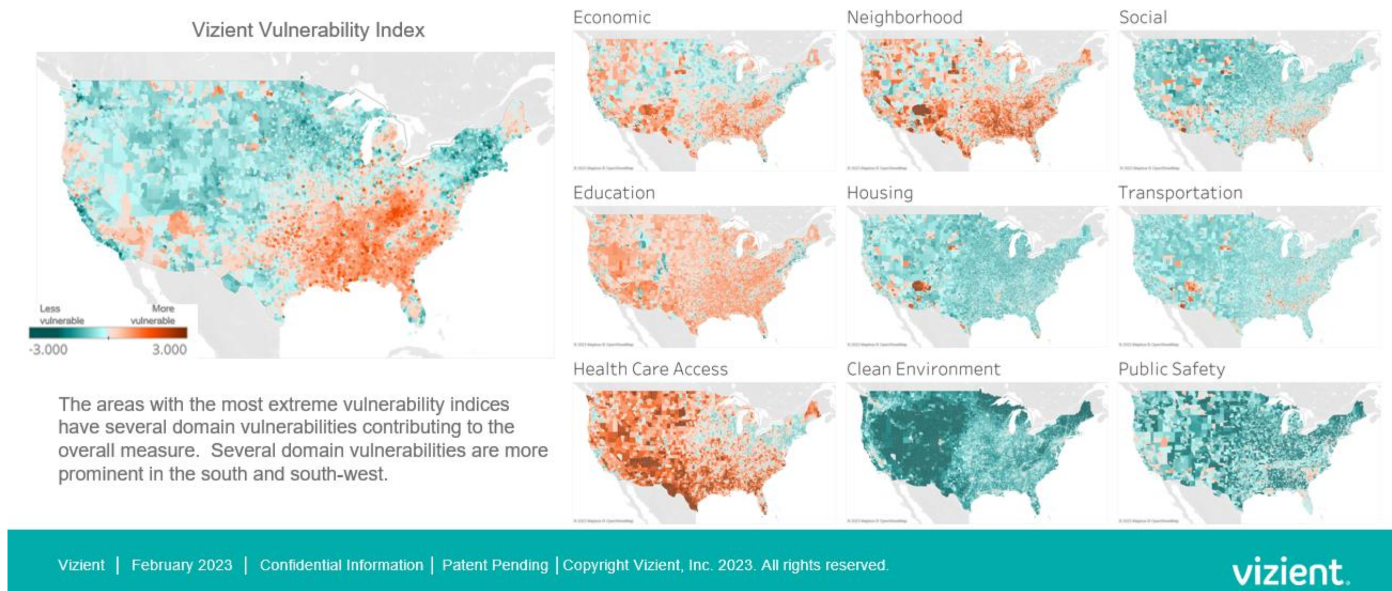

Figure 2. Various maps demonstrating variable SDOH domain weighting as found when using the VVI™

Future Use of the HEI

As CMS is developing other health equity-focused policies, including those that use an area-level index, it is unclear to stakeholders whether policies provided in the Proposed Rule will extend to other programs (e.g., Medicare Shared Savings Program, ACO REACH) or future policies (e.g., Hospital Readmissions Reduction Program risk adjustment). While Vizient agrees with CMS regarding the limitations of the ADI, we note that varying policy or positions regarding use of indices to support health equity may create confusion unless clear distinctions are highlighted. Finally, as there remains several questions about the goals of the HEI reward, Vizient reiterates our request that CMS clarify its long-term goals for the HEI and other applications that the agency is considering, as this will help inform stakeholder comments.

Conclusion

Vizient thanks CMS for the opportunity to comment on the Proposed Rule, which would meaningfully help address challenges related to utilization management, including prior authorization processes for providers and patients. We also thank the agency for working to develop policies to help support health equity.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation’s top health care providers. In closing, on behalf of Vizient, I

would like to thank the CMS for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
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Appendix 1. Comparison of Various Area-Level Indices

	Area Deprivation Index	Social Deprivation Index	Community Resilience Estimates	Vizient Vulnerability Index
Data granularity	× County × Zip Code × Census Tract ✓ Block Group	✓ County ✓ Zip Code ✓ Census Tract × Block Group	✓ County × Zip Code ✓ Census Tract × Block Group	✓ County ✓ Zip Code ✓ Census Tract ✓ Block Group
Timeliness	Updated in 2015 and 2019	2012 and 2015	Updated annually	Updated annually
Social Determinants of Health Domains	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Access to Health Care ✓ Transportation ✓ Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Access to Health Care ✓ Transportation ✓ Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing × Access to Health Care × Transportation ✓ Social Environment × Physical Environment × Public Safety	✓ Income & Wealth ✓ Employment ✓ Education ✓ Housing ✓ Access to Health Care ✓ Transportation ✓ Social Environment ✓ Physical Environment ✓ Public Safety
Intent	Mortality rate prediction	Health resource allocation	Assessing potential impact of disasters including COVID-19	Describes differences in life expectancy representing differences in chronic disease incidence and management
Health Care Focus	✓ Life Expectancy / Mortality × Chronic Disease Prevalence ✓ Readmissions × ED utilization × Maternal Health	✓ Life Expectancy / Mortality ✓ Chronic Disease Prevalence × Readmissions × ED utilization ✓ Maternal Health	× Life Expectancy / Mortality × Chronic Disease Prevalence × Readmissions × ED utilization × Maternal Health	✓ Life Expectancy / Mortality ✓ Chronic Disease Prevalence ✓ Readmissions ✓ ED utilization ✓ Maternal Health
Measurement Focus	17 components 2 components account for almost all of the variation (income and housing) Poor fit to life expectancy (r^2 0.25)	9 components, including race (Black), gender and age (women 15-44) No serious issues with partial correlations Moderate fit to life expectancy (r^2 0.56)	7 household risk factors and 3 individual risk factors, including age (>64) Population with $\geq$3 risk factors has a moderate fit to life expectancy (r^2 0.44)	43 components in 9 domains. All are significant in different locations Good fit to life expectancy (r^2 0.87)
Geospatial Adjustments	Single index algorithm for the whole country	Single index algorithm for the whole country	Single index algorithm for the whole country	Index adapts to local relevance of each domain as it correlates with life expectancy

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