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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 and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization (PA) Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program (RIN 0938-AU87)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to respond to the proposed rule that aims to improve data sharing and streamline the PA process by providing new requirements for a range of plans and payers, including Medicare Advantage (MA) organizations and Medicaid managed care plans (hereinafter "Proposed Rule"). Vizient applauds CMS for issuing a request for information (RFI) regarding MA, to which Vizient commented in August 2022, and for using such feedback to develop 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 streamline PA processes and advance interoperability. In addition, we thank the agency for continuing to seek stakeholder input as regulatory approaches to advance heath equity are being considered. Vizient offers the

following recommendations for the agency's consideration as related to PA, interoperability, and health equity.

Patient Access API

In the Proposed Rule, CMS seeks to expand current Patient Access API requirements to include PA information by January 1, 2026. Vizient appreciates efforts to engage patients in care and improve care coordination. Should the agency finalize this policy, we encourage the agency to consider opportunities to educate patients regarding the PA process. Vizient agrees that sharing information with providers is critical, but it will also be important for patients to be aware of providers' limitations regarding PA decisions. In addition, given CMS anticipates that patients would share information with providers, we encourage the agency to also test this flow of information and ease of sharing information with providers.

CMS proposes that impacted payers would report Patient Access API metrics to CMS on an annual basis and that this information would be used for oversight purposes. Vizient believes it is important that CMS be able to quickly respond to noncompliance with the Patient Access API and that annual reporting will not adequately address this concern. As such, Vizient encourages CMS to consider more frequent reporting by payers given the important role PA plays in patient access to care and the ongoing harm that patients may endure should efforts to streamline the PA process be slowly adopted.

CMS also provides additional information regarding the proposed payer-reported metrics[1] in the Proposed Rule. Vizient is concerned that reporting such metrics may not adequately reflect progress related to the streamlining of PA processes from the patient perspective. For example, as provided in the Proposed Rule, the number of beneficiaries who requested that data be transferred via the Patient Access API to a health app would not be reflected in the metrics reported. Rather, the metrics would only reflect the number of unique patients where such data transfer was successful. Also, the proportion of patients whose coverage depends on PA decisions would similarly be unknown. Vizient encourages CMS to explore additional metrics that better reflect patient requests and the outcomes of those requests.

In addition, CMS indicates that it does not plan to publicly report these metrics at the state, plan or issuer level but may reference or publish aggregated and de-identified data. From the Proposed Rule, it is unclear as to why CMS is not proposing to publicly report plan reported information at the state, plan or issuer level. Vizient encourages CMS to clarify this information before finalizing the proposed policy and to consider publicly reporting this information.

Lastly, while the proposed policies do not apply to drugs, Vizient urges CMS to consider policies that require impacted payers to include information about PA for drugs (e.g., when the

[1] Examples of metrics proposed to be reported include the total number of unique patients whose data is successfully transferred via the Patient Access API to a health app designated by the patient and the total number of unique patients whose data is transferred more than once via the Patient Access API to a health app designated by the patient.

payer covers drugs via the Patient Access API and the Payer-to-Payer API). Vizient believes such information, like the other PA proposals, will help streamline care and support care coordination. Further, inclusion of medications will help limit circumstances where care information is bifurcated or otherwise not accessible, which can be disruptive and create unnecessary confusion.

Provider Access API

CMS proposes to require impacted payers to implement and maintain a Fast Health Interoperability Resources (FHIR) API to exchange data with providers (Provider Access API) and other related requirements (e.g., sharing requested data no later than one business day after the provider initiates the request). Vizient supports the agency's Provider Access API proposal but encourages the agency to consider a shorter timeframe to share requested data. For example, one business day over a long weekend could delay care and the provider and payer may operate on different schedules. To improve clarity, Vizient suggests plans make clear once they have received a request and the specific date on which a provider should expect to receive information from the plan.

In the Proposed Rule, CMS seeks comment on potentially requiring plans to share patient data with out-of-network providers instead of only in-network providers. PA policies impose significant administrative burden to both in-network and out-of-network providers which have downstream consequences for patients. Given the Proposed Rule currently focused on in-network providers, out-of-network providers will continue to face the same prior authorization challenges. To help address this concern, Vizient encourages CMS to consider requirements for plans to support out-of-network providers' access to patient data and the other functionalities associated with the Provider Access API.

Also, CMS requests comments on whether it should develop additional guidance or regulation on the specific content of the educational materials about the Provider Access API. Vizient strongly encourages additional information and education regarding the Provider Access API, including efforts to ensure consistency among plans which may be supported through additional guidance or regulation related to education. Vizient encourages CMS to work closely with providers to better understand educational needs and how to coordinate such education among plans to promote consistency.

Lastly, CMS indicates the Provider Access API would enable current patients' information to be exchanged from payers to providers that are in that payer's network, at the provider's request. To the extent CMS is considering additional requirements on providers to support implementation via the Medicare fee-for-service program, we encourage the agency to minimize provider burden. Given such an API should help streamline care, providers will likely already be incentivized to utilize the Provider Access API. Further, since the Provider Access API policy has yet to be finalized or implemented, it is premature to impose additional requirements on providers via the Medicare fee-for-service program.

Improving PA Processes

CMS proposes to require payers to take the following four key steps to improve PA processes by January 1, 2026: implement and maintain an API to support the PA process; respond to PA requests within specified timeframes; provide a reason for PA denials; and require public reporting on PA outcomes. Vizient applauds CMS for proposing meaningful reforms to help improve PA processes which will help minimize burden and improve patient access to care.

Implement and maintain an API to support and streamline the PA process (known as the PA Requirements, Documentation and Decisions (PARDD) API)

CMS proposes that payers would be required to implement the PARDD API for all PA rules and requirements for items and services, excluding drugs, by January 1, 2026. Vizient encourages CMS to consider broadening such requirements so that drugs, including those traditionally provided under the medical benefit, may be included among the items and services impacted by the Proposed Rule. Like other items and services, medications are commonly subject to PA requirements and, as a result, pose significant burden to providers and, more importantly, impede patient access to needed treatments. Thus, Vizient urges CMS to expand PA policies to address medication access issues as well.

Respond to PA requests within specified timeframes

CMS proposes to modify the timeframes by which impacted payers must respond to PA requests. Specifically, impacted payers would need to respond to PA requests within 72 hours for expedited (urgent) requests and seven calendar days for standard (non-urgent) requests, unless a shorter minimum timeframe is established under state law. Vizient believes that the proposed timeframes are excessively long and do not adequately reflect the sense of urgency that is needed when care decisions need to be made. For example, urgent requests that would take up to 72 hours could result in critical time being lost that would have improved a patient's outcome while resources and time are wasted waiting on a response from the payer. In addition, in circumstances where lab tests are needed, a 72-hour delay may compromise the ability to start treatment in a timely manner. Vizient urges CMS to adopt shorter timeframes, including a maximum of 24 hours for expedited requests and 72 hours for standard requests.

In addition, CMS clarifies that it is not proposing to require that impacted payers approve a PA request should that payer not respond within the required decision timeframes. The agency also notes that some programs, such as Medicare Advantage, have regulations which include provisions for the failure to provide timely notice of a determination, which constitutes an adverse decision that may be appealed. Vizient is concerned that, as proposed, payers would have little incentive to devote additional time and resources to PA review, including sharing adverse decisions, if a denial is effectively presumed. Vizient recommends CMS propose a policy requiring that PA requests be presumed approved should the standard or expedited decision timeframes not be met by the payer.

Provide a clear reason for PA denials

CMS proposes that, beginning January 1, 2026, impacted payers would be required to provide a specific reason for denied PA decisions, regardless of the method selected by the provider to send the PA request. Vizient agrees with the need for plans to share clear reasons for PA denials, including when providers send PA requests in different ways. We encourage CMS to work with providers to better determine whether plan-provided reasons are adequately clear and suggest a process be identified to update standardized language (e.g., from a selection menu) regarding why a PA request was denied should that be how denial reasons are shared.

Also, as noted above, Vizient is concerned that PA denials will unnecessarily occur more frequently if plans do not meet the specified timeframes. As a result, should CMS finalize policy decision timeframes without adopting our recommendation regarding the denial presumption, we suggest that it be made clear that the denial was due to the timeframes not being met to better identify the frequency in which this circumstance occurs.

Public reporting on PA outcomes

CMS proposes to require impacted payers to publicly report on certain metrics annually, such as the percentage of standard PA requests that were approved, aggregated for all items and services; the percentage of standard PA requests that were denied, aggregated for all items and services; and the percentage of standard PA requests that were approved after appeal, aggregated for all items and services. Vizient believes more detailed PA statistics will provide greater transparency and potentially identify which procedures may be particularly troublesome from a PA perspective (e.g., high denial rates). Further, this information may also help providers develop new practices to reduce denials and may be of interest to patients as they select plans. While Vizient supports inclusion of these and other proposed metrics in the public reporting requirements, we also suggest that PA statistics about more specific items and services be provided as opposed to only aggregated information for all items and services.

Potential Application for Medicare Fee-for-Service (FFS)

While the Proposed Rule does not apply to Medicare FFS, CMS notes Medicare FFS is evaluating opportunities to improve automation of PA processes and whether the Proposed Rule's policies could be implemented for the FFS program. Vizient believes efforts to streamline PA processes are helpful, but we still have concerns regarding the proliferation of PA policies by a range of payers, including traditional Medicare, especially when such policies do not effectively reduce unnecessary interventions and, in fact, ultimately lead to interruptions in patient care. Thus, while Vizient is supportive of the agency's efforts to streamline PA processes across all payers, we caution that improved PA processes should not be used as justification to add more PA policies in traditional Medicare given the negative implications to patient care.

Gold-Carding for Prior Authorization

CMS seeks comment for future rulemaking on how to measure whether and how gold-carding[2] or PA exemption programs could reduce provider and payer burden and improve services to patients. Vizient providers value these programs, which they say significantly reduce burdens and improve continuity of care. Vizient encourages CMS to identify opportunities to support expansion of such programs.

As part of this effort, Vizient suggests CMS provide guidance to payers so that more providers may be consistently eligible for gold-carding or PA exemption programs. For example, additional information regarding the metrics used to identify providers for gold-carding programs could be shared as an initial step to promote greater consistency between such programs. CMS could then use this information to work with providers to develop guidance or regulations to ensure consistency among payers.

Enforcement

Vizient applauds the agency's efforts to streamline PA processes by providing several new requirements for payers. In the Proposed Rule, CMS indicates that it would enforce certain new proposals based on the existing compliance policies for impacted payers. Vizient encourages the agency to better clarify enforcement mechanisms and oversight of payers. Given the significant barrier to care that PA policies can pose, we believe it is imperative that additional efforts are made to ensure plan compliance.

Electronic PA for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

In the Proposed Rule, CMS proposes a new measure for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS, as well as for eligible hospitals and Critical Access Hospitals (CAHs) under the Medicare Promoting Interoperability Program, related to electronic PA.[3] Vizient is concerned that the agency is proposing a measure where

[2] As provided in the Proposed Rule, "Some payers have implemented what they term "gold-carding" or similar program to relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance. In such programs, providers are relieved of requirements to submit prior authorization requests based on data indicating their adherence to submission requirements, appropriate utilization of items or services, or other evidence-driven criteria."

[3] Electronic Prior Authorization measure description: For at least one hospital discharge and medical item or service (excluding drugs) ordered during the EHR reporting period, the prior authorization is requested electronically from a PARDD API using data from CEHRT. The hospital or CAH would also be required to report the numerator and denominator for the measure or report an exclusion. Numerator: The number of unique prior authorizations in the denominator that are requested electronically from a PARDD API using data from CEHRT. Denominator: The number of unique prior authorizations requested for medical items and services (excluding drugs) ordered for patients discharged from the eligible hospital or CAH inpatient or emergency department (place of service (POS) code 21 or 23) during the EHR reporting period, excluding prior authorizations that cannot be requested using the PARDD API because the payer does not offer an API that meets the PARDD API requirements outlined in section II.D.3.a of the Proposed Rule. Exclusions: Any eligible hospital or CAH that: (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable EHR reporting period; or (2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the PARDD API requirements outlined in section II.D.3.a of this proposed rule during the applicable EHR reporting period.

fundamental elements of the measure (i.e., PARDD API) have yet to be finalized or implemented. As a result, real-world experiences have yet to be learned which could impact comments regarding the measure design. Vizient suggests CMS defer imposing new measures on providers until providers can gain more experience with PARDD API and more meaningfully share input regarding the measure's specifications.

Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

Vizient supports CMS's continued efforts to reduce health inequities by integrating health equity-related work into the agency's programs. We also support comments and feedback provided by Aligning for Health which, in its comments, further detail the need for integrated and coordinated programs to better improve health outcomes.

Also, Vizient notes that recent efforts to develop more robust data standards from the Office of the National Coordinator for Health Information Technology (ONC) are a positive step towards addressing data exchange issues. However, barriers still exist. As CMS is aware, recent versions of the United States Core Standards for Data Interoperability (USCDI) have evolved to include data elements related to social determinants of health (SDoH) but broad adoption has yet to occur by all providers, such as those who were not incentivized to use Certified Electronic Health Record Technology or who required a hardship exception from the Promoting Interoperability Program. Further, data standards and technological infrastructure used by community-based organizations (CBOs) may be less developed and incompatible. Vizient supports collaboration among stakeholders aiming to reduce inequities and encourages providing incentives, opposed to penalizing providers or adding unnecessary administrative burden, to support such work.

What are best practices regarding frequency of collection of social risk and social needs data? What are factors to be considered around expiration, if any, of certain social needs data?

Collecting social risk data and understanding the social needs of a patient is critical to providing robust care. However, collecting social risk data can often be challenging for providers because there is a lack of consistency in the screening tools available.[4] Variability in these tools without data collection practices or standards that can identify tools used, or crosswalking of terminology and questions, could detract from efforts to identify social risks and support patients. Further, differing perspectives on the right screening tool could lead to patients being asked too frequently similar questions without the ability to measure progress or support interventions.

When considering best practices for data collection, it is important to consider that many data collection tools in healthcare facilities rely on filling out a form. However, more effective ways to capture a patient's lived experience with social needs exist. For example, patients may not

[4] https://sirenetwork.ucsf.edu/SocialNeedsScreeningToolComparisonTable

understand the context of the question or choose to skip questions on a form rather than asking for clarity, including why the question is relevant to their care. Vizient recommends that CMS work with stakeholders to utilize more conversational methods of data collection that can help ensure a patient feels comfortable discussing social needs information.

Vizient also encourages CMS to consider the patient care journey. For example, a visit with a primary care doctor may be a better place to collect social needs data than an emergency visit given the patient's relationship with the provider and circumstance of care. As the agency explores opportunities to collect this information, it is also important that reimbursement options be made available to providers to support such screening. Further, a provider should not be penalized when a patient's social needs persist particularly given many social needs may be beyond the provider's locus of control.

Lastly, should patient information be collected by different providers or payers, it is important that this information be shared to identify where potential differences exist as this could signal a change of circumstances and prompt additional communications with the individual.

What are the challenges in representing and exchanging social risk and social needs data from different commonly used screening tools? How do these challenges vary across screening tools or social needs (for example, housing, food)?

As previously noted, one key challenge in collecting and sharing social needs data is a lack of consistency and standardization. Vizient has advocated for greater consistency and standardization in prior comments to CMS, noting that the lack of clear definitions and the varying tools produce data that is less meaningful or actionable when aiming to address inequities and measure improvement.

What are the barriers to the exchange of social risk and social needs data across providers? What are key challenges related to exchange of social risk and social needs data between providers and community-based organizations?

Barriers to the exchange of social risk and social needs data across providers include variable systems for collecting and sharing data, in addition to challenges in communicating information as a patient may see multiple providers. For example, an emergency room physician may have limited insight regarding a patient's previously collected social needs information if they are operating in an emergency circumstance where the need to learn such information is outweighed by time sensitive care needs. Further, provider-to-provider data sharing can be challenging given different work hours, internal practices and interoperability issues.

Providers and CBOs may also have challenges collecting social needs data because of a lack of staffing, technological infrastructure and time. Providers may also lack the ability to connect patients with appropriate community resources for a variety of reasons, including challenges in identifying such resources and referring patients, in addition to provider uncertainty regarding appropriate data sharing that complies with HIPAA. To help overcome these barriers, resources and education to both healthcare providers and CBOs could help facilitate stronger relationships between these types of entities. Also, legislative solutions (e.g., the Consolidated

Appropriations Act, 2023 (CAA, 2023) included language from the Leveraging Integrated Network in Communities (LINC) to Address Social Needs Act) which would enable states, through public-private partnerships, to leverage local expertise and technology to overcome longstanding challenges in helping to connect people to different supports services. We encourage CMS to work with the Department of Health and Human Services (HHS) to make funding available as it would help support the infrastructure needed to collect and share social risk factors data.

How can payers promote exchange of social risk and social needs data? Are there promising practices used by MA organizations, state Medicaid agencies, Medicaid managed care plans, commercial health plans, or other payers that can potentially be further leveraged in other settings?

Payers can promote the exchange of social risk and social needs data by sharing patient-level data with the providers. As Vizient has noted in previous comments, payers may be better able to address certain social risk factors, such as lack of transportation or food insecurity. As payers are more consistently collecting social risk and social needs data, we suggest efforts be made to share such information with providers.

Please identify opportunities and approaches that would help CMS facilitate and inform effective infrastructure investments to address gaps and challenges for advancing the interoperability of social risk factor data.

Addressing health equity will require providers and community organizations to work collaboratively on interventions at the individual level, among other efforts. As CMS develops approaches to advance the interoperability of social risk factor data, Vizient urges CMS to focus on approaches within its programs that are within the provider's locus of control. Vizient would have concerns if CMS proposed policies that would mandate providers and CBOs to collaborate because such collaboration may be limited for reasons beyond the provider's control, including in situations where CBOs are unavailable.

Lastly, Vizient encourages CMS to consider using the Vizient Vulnerability Index™ (VVI™)to help identify community-level vulnerabilities by social determinant of health domain. The VVI™ is a community-level index that is designed specifically for health equity purposes. As shown in Figure 1, the VVI™ highlights the impact of different SDoH domains across the country. Such information would be critical to identifying which domain contributes most to inequities in a given area and, as a result, would be critical information to consider when making investment decisions. For example, if a community is identified as being particularly vulnerable because it is in a food desert, then the agency could consider opportunities to better connect providers to food banks and other CBOs that aim to support access to nutritious food. Vizient welcomes the opportunity to discuss this further with CMS.

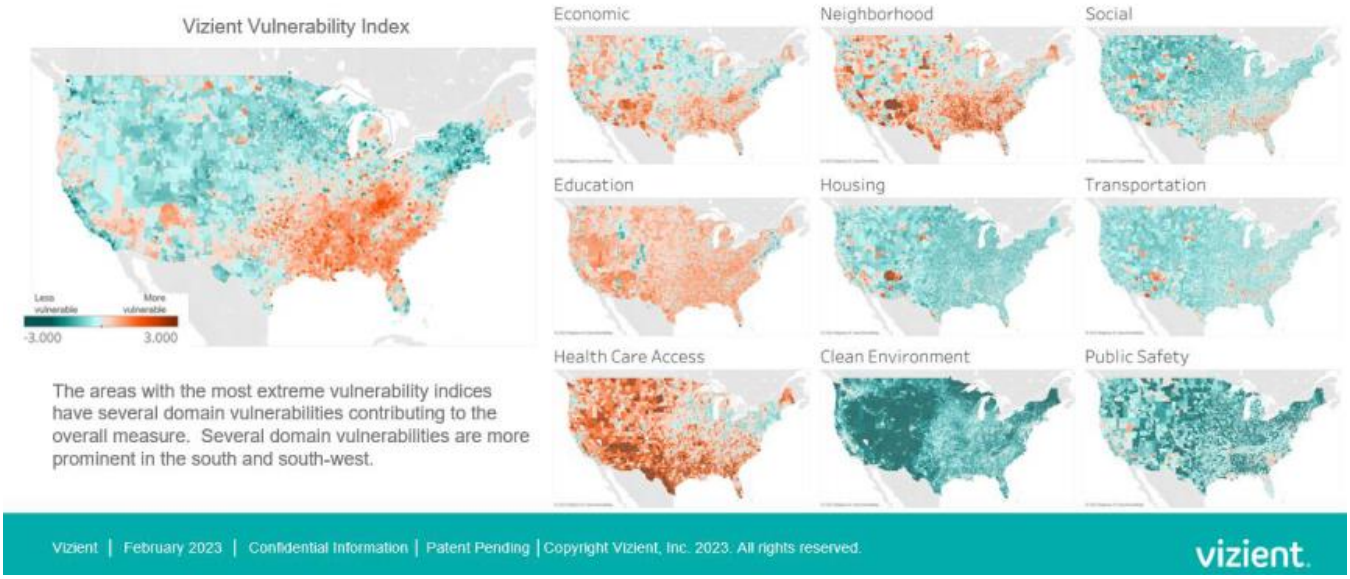

Figure 1. Various maps demonstrating variable social determinants of health domain weighting as found when using the Vizient Vulnerability Index™

Conclusion

Vizient thanks CMS for the opportunity to comment on the Proposed Rule, which would meaningfully help address challenges related to PA processes for providers and patients, and support future health equity-focused policies.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated healthcare 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 healthcare 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,

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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 ≥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