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The Patient's Voice: Legal Implications of Patient-Reported Outcome Measures

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The Patient's Voice: Legal Implications of Patient-Reported Outcome Measures

Sharona Hoffman[†] and Andy Podgurski^{††}

ABSTRACT

In recent years, the medical community has paid increasing attention to patients' own assessments of their health status. Even regulatory agencies, such as the Food and Drug Administration and the Centers for Medicare and Medicaid Services, are now interested in patient self-reports. The legal implications of this shift, however, have received little attention. This Article begins to fill that gap. It introduces to the legal literature a discussion that has been ongoing in the health care field.

Patient-reported outcome measures (PROMs) are reports of patients' symptoms, treatment outcomes, and health status that are documented directly by patients, typically through electronic questionnaires. In this era of growing efforts to control health care costs, improve care delivery, and combat physician burnout, patients' own input can be invaluable for clinicians as well as researchers, regulators, and insurers. At the same time, however, PROMs have a number of pitfalls, and the implementation of PROM programs is challenging and complex.

The Article argues that health care providers should be keenly aware of potential medical malpractice risks associated with PROMs. In addition, because PROMs collect a plethora of sensitive information about pain, sexual function, anxiety, and other matters, the HIPAA Privacy Rule should be revised to address PROMs specifically. The Article further posits that it would be premature for regulatory agencies or private insurers to require PROM submission at this time. It also details strategies, such as use of artificial intelligence, to strengthen PROMs and facilitate their integration into clinical practice and other arenas.

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INTRODUCTION

Anyone who reads the news or follows policy debates is aware of grave concerns about the U.S. health care system. A typical article from *Harvard Health Publishing* begins as follows: “Here’s a question that’s been on my mind and perhaps yours: Is the US healthcare system expensive, complicated, dysfunctional, or broken? The simple answer is yes to all.”¹ In an effort to address some of the system’s grave shortcomings, health care and policy experts have developed concepts such as value-based care² and comparative effectiveness research.³ They

¹ Robert H. Shmerling, *Is our Healthcare System Broken?*, HARVARD HEALTH PUBLISHING, July 13, 2021, <https://www.health.harvard.edu/blog/is-our-healthcare-system-broken-202107132542>.

² John E. McDonough & Eli Y. Adashi, *The Center for Medicare and Medicaid Innovation – Toward Value-Based Care*, 327 JAMA 1957, 1957, 1957 (2022) (“the drive for value-based care remains widely endorsed by both political parties and across most segments of the health care sector”); Lucas Pantaleon, *Why Measuring Outcomes Is Important in Health Care*, 33 J. VET. INTERN. MED. 356, 356 (2019) (“A new strategy has been introduced in human health care, namely, achieving the best outcomes for the lowest cost and thus maximizing value for patients”); Cleveland Clinic, *Value-Based Care*, <https://my.clevelandclinic.org/health/articles/15938-value-based-care> (last reviewed Oct. 19, 2020) (explaining that value-based care is “the idea of improving quality and outcomes for patients” through standardizing “healthcare processes through best practices, as in any business”).

³ INSTITUTE OF MEDICINE. INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH 13 (2009) (“Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat,

are also harnessing big data and artificial intelligence to benefit patients.⁴ Improving the system using any of these strategies, however, will depend on validly measuring health care outcomes.⁵

This Article focuses on a particular means of assessing health care outcomes, called patient-reported outcome measures (PROM).⁶ Little has been written thus far about the legal implications of PROM use, and PROMs are largely absent from the legal literature.⁷ This Article begins to fill that gap, providing an overview of legal and technical PROM-related concerns. It introduces to the legal literature a discussion that has been ongoing in the medical community.⁸ Such analysis is particularly timely because the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) have begun using PROMS for regulatory purposes.⁹ For example, approximately twenty-six percent of new drugs approved between 2016 and 2020 included patient reported outcome-related statements in labeling.¹⁰

Traditionally, individual and population health care outcomes have been assessed based on clinical measures such as mortality, number of hospital-acquired infections, number of avoidable hospital readmissions, blood pressure changes, and blood sugar levels.¹¹ But what about patients' own voices? Aren't patients' feelings

and monitor a clinical condition or to improve the delivery of care"); Amit Dang & Kirandeep Kaur, *Comparative Effectiveness Research and Its utility in In-Clinic Practice*, 7 PERSPECT. CLIN. RES. 9, 9-10 (2016).

⁴ Yan Cheng Yang, Saad Ul Islam, Asra Noor, Sadia Khan, Waseem Afsar & Shah Nazir, *Influential Usage of Big Data and Artificial Intelligence in Healthcare*, 2021 COMPUT. MATH METHODS MED., Sept. 6, 2021:5812499, 1.

⁵ 42 U.S.C. § 1320e(a)(2)(A) (explaining that comparative effectiveness research involves "evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items..."); Thomas Davenport A. & Ravi Kalakota, *The Potential for Artificial Intelligence in Healthcare*, 6 FUTURE HEALTHCARE J. 94, 94 (2019) (explaining that machine learning applications (a common form of AI) most often need to be trained on datasets with known outcome variables); Pantaleon, *supra* note 2, at 356 ("In value-based care, the only true measures of quality are the outcomes that matter to patients.").

⁶ Centers for Medicare & Medicaid Services, *Patient Reported Outcome Measures*, May 2022, <https://mmshub.cms.gov/sites/default/files/Patient-Reported-Outcome-Measures.pdf> [hereinafter CMS 2022].

⁷ NATIONAL QUALITY FORUM, PATIENT-REPORTED OUTCOMES: BEST PRACTICES ON SELECTION AND DATA COLLECTION 23 (2020), https://www.qualityforum.org/Publications/2020/09/Patient-Reported_Outcomes_Best_Practices_on_Selection_and_Data_Collection_-_Final_Technical_Report.aspx ("Legal considerations are generally unexplored currently.").

⁸ See e.g. Samantha Cruz Rivera et al., *Ethical Considerations for the Inclusion of Patient-Reported Outcomes in Clinical Research: The PRO Ethics Guidelines*, 327 JAMA 1910, 1910-19 (2022).

⁹ See *infra* Parts III.B and IV.

¹⁰ Ari Gnanasakthy, Lindsey Norcross, Carla (DeMuro) Romano & Robyn T. Carson, *A Review of Patient-Reported Outcome Labeling of FDA-Approved New Drugs (2016-2020): Counts, Categories, and Comprehensibility*, 25 VALUE IN HEALTH 647, 650 (2022). For a discussion of labeling, see *infra* note 271 and accompanying text.

¹¹ Martha Hostetter & Sarah Klein, *Using Patient Reported Outcomes to Improve Health Care Quality*, COMMONWEALTH FUND NEWSLETTER,

about whether medical interventions improved or diminished their quality of life equally significant? And what about important values that cannot be clinically measured, such as pain, anxiety, or sexual functioning?¹²

In some instances, patients receive medications for their ailments (e.g. a rash or joint pain) but are not asked to return for follow-up visits. In those instances, physicians may obtain no information about treatment outcomes at all. In the absence of follow-up assessments, it may be difficult to determine which therapies work best for patients. This is a problem not only for individual patients and physicians but also for medical science in general.

PROMs can fill these data vacuums. PROMs can be defined as reports of the “status of a patient’s health condition that come [] directly from the patient without interpretation of the patient’s response by a clinician or anyone else.”¹³ An additional type of input is the patient-reported experience measure (PREM), which refers to patients’ perceptions of their interactions with the health care system or clinicians.¹⁴ This Article focuses on PROMs, which measure patients’ symptoms, functionality, and quality of life.¹⁵

PROMs typically take the form of surveys that patients are asked to complete.¹⁶ They can be used for a variety of purposes. First and foremost, they are used in clinical care to inform physicians about patients’ conditions and assist them in making diagnostic and treatment decisions.¹⁷ In addition, PROMs are employed for purposes of 1) clinical research, including comparative effectiveness studies, 2)

<https://www.commonwealthfund.org/publications/newsletter-article/using-patient-reported-outcomes-improve-health-care-quality>.

¹² See e.g. William A. Fisher et al., *Standards for Clinical Trials in Male and Female Sexual Dysfunction: II*.

Patient-Reported Outcome Measures, 13 J SEX. MED. 1818, 1818 (2016) (“PROs are essential for assessing male and female sexual dysfunction and treatment response, including symptom frequency and severity, personal distress, satisfaction, and other measurements of sexual and general health-related quality of life.”).

¹³ Michael Fleischmann & Brett Vaughan, *The Challenges and Opportunities of Using Patient Reported Outcome Measures (PROMs) in Clinical Practice*, 28 INT’L J. OSTEOPATHIC MED. 56, 56 (2018).

¹⁴ Anne Neubert et al., *Understanding the Use of Patient-Reported Data by Health Care Insurers: A Scoping Review*, 15 PLOS ONE e0244546 (2020), p. 2; Barak D. Richman & Kevin A. Schulman, *Are Patient Satisfaction Instruments Harming Both Patients and Physicians?*, 328 JAMA 2209, 2209-10 (2022).

¹⁵ Joanne Greenhalgh et al., *How Do Patient Reported Outcome Measures (PROMs) Support Clinician-Patient Communication and Patient Care? A Realist Synthesis*, 2 J. PATIENT-REPORTED OUTCOMES 42, 45 (2018).

¹⁶ See *infra* notes 28-37.

¹⁷ Ian Porter et al., *Integrating Patient Reported Outcome Measures (PROMs) into Routine Nurse-Led Primary Care for Patients with Multimorbidity: A Feasibility and Acceptability Study*, 19 HEALTH QUAL. LIFE OUTCOMES 133, 134 (2021).

quality improvement initiatives, 3) FDA oversight and labeling, and 4) performance measurement and other assessments by insurers.¹⁸

PROMs have many potential benefits, especially when employed in conjunction with clinician-reported outcomes and administrative data.¹⁹ They can promote more informed clinical decision making, improve physician-patient communications, and foster patient empowerment.²⁰ But they come with a number of pitfalls and shortcomings.²¹

One of us has personal experience with PROMs. Professor Podgurski has Parkinson's disease. One neurologist's office routinely gave him a tablet computer and asked him to complete long questionnaires prior to each of his appointments. He did this with difficulty because of his limited dexterity and because he felt pressured to complete the survey quickly, before being called in to see the doctor. Yet, the doctor never mentioned the PROMs and seemed unaware of the information Professor Podgurski provided. Such experiences can cause patients to feel frustrated and resentful.

More serious shortcomings exist as well. For example, PROM surveys may not be validated and reliable and thus be of poor quality.²² Patients may not fully answer all survey questions, thus providing incomplete data.²³ Patients' responses may be biased by a desire to please the physician or by personality traits that influence their tolerance for discomfort.²⁴ An additional problem for research initiatives is that the group of patients who cooperate in completing PROMs may not be representative of the patient population as a whole, thereby yielding biased research results.²⁵

Health care providers may have their own difficulties with PROMs. Physicians may not know how to interpret PROM scores or determine if score changes are clinically meaningful.²⁶ Clinicians may also feel that they are already overwhelmed

¹⁸ Neubert et al., *supra* note 14, at 1; Lee Squitieri, Kevin J. Bozic & Andrea L. Pusic, *The Role of Patient-Reported Outcome Measures in Value-Based Payment Reform*, 20 *VALUE IN HEALTH* 834, 834 (2017); Rahma Warsame & Anita D'Souza, *Patient Reported Outcomes Have Arrived: A Practical Overview for Clinicians in Using Patient Reported Outcomes in Oncology*, 94 *MAYO CLIN. PROC.* 2291, 2292-98 (2019); Massachusetts Medical Society, *Patient-Reported Outcome Measures: Current State and MMS Principles* (2018), <https://www.massmed.org/proms/>.

¹⁹ Fatima Al Sayah, Markus Lahtinen, Gouke J. Bonsel, ARto Ohinmaa & Jeffrey A. Johnson, *A Multi-Level Approach for the Use of Routinely Collected Patient-reported Outcome Measures (PROMs) Data in Healthcare Systems*, 5 (suppl. 2) *J. PATIENT REP. OUTCOMES* 98, 1 (2021).

²⁰ *See infra* Part I.B.

²¹ Al Sayah et al., *supra* note 19 at 4.

²² *See infra* Part I.C.1.a.

²³ *See infra* Part I.C.1.d (discussing missing data).

²⁴ *See infra* Part I.C.1.b (discussing response shift and response bias).

²⁵ *See infra* notes 146-157 and accompanying text.

²⁶ *See infra* Part I.C.1.e (discussing PROM interpretability).

and burnt out and that adding PROM use to their workload stretches them further towards the breaking point.²⁷

These challenges and others generate several legal concerns. Because PROMs may solicit sensitive information about patients' quality of life, they raise questions about the adequacy of medical privacy protections. In addition, clinicians may rightly worry about medical malpractice liability associated with PROMs. The appropriateness of using PROMs for regulatory or reimbursement purposes is also open to debate.

The remainder of the paper proceeds as follows. Part I discusses the attributes, benefits, and risks of PROM use. Part II focuses on the clinical use of PROMs and analyzes privacy and medical malpractice concerns. It examines relevant HIPAA Privacy Rule requirements and exemptions that could threaten PROM confidentiality. In addition, this section posits that PROM use can generate malpractice risks for clinicians and health care entities under a variety of circumstances. These include health care providers ignoring data that are disclosed in PROMs to the detriment of patients, relying on PROMs excessively when other diagnostic tools should have been used, or failing to implement PROMs when doing so has become the standard of care.

Part III assesses PROM use in research and FDA regulation. It highlights critiques of current PROM utilization in clinical studies. It also discusses the FDA's acceptance of PROMs for medical device assessment and labeling purposes. Part IV focuses on PROM use for performance measurement and insurance coverage.

Part V formulates recommendations to address PROM-related legal concerns. It develops technical and administrative recommendations for PROM selection and implementation that would reduce the likelihood of malpractice claims and enhance PROM integrity. These include automation of PROM review using artificial intelligence, psychometric evaluations, pilot programs, stakeholder input, and more. Part V also recommends enhanced vigilance regarding data security, a modification to the HIPAA Privacy Rule, the development of clinical practice guidelines regarding PROM use, and patient education and notice concerning PROMs. Additionally, it outlines how PROMs might be used to support either plaintiffs or defendants in malpractice litigation. Part V further argues that it is premature for the FDA and CMS to mandate PROM use because of this tool's potential weaknesses. At the same time, financial incentive programs for voluntary PROM adopters are desirable. Part VI concludes.

I.

PROMS ATTRIBUTES, BENEFITS, AND RISKS

²⁷ See *infra* Part I.C.2.b.

PROMs can offer important insights into patient welfare, but they must be expertly selected and implemented. This Part discusses the nature of PROMs along with their benefits and pitfalls.

A. What Are PROMs?

PROMs are usually standardized questionnaires that solicit patients' input about their general health status and specific medical conditions.²⁸ They focus on patients' perceptions of their symptoms, ability to function, health behaviors, health care experience, and health-related quality of life.²⁹ PROM scores can be compared over time to determine the efficacy of medical interventions.³⁰ Patients can be asked to answer questionnaires online before or after their visits or can be given tablet computers to work with at the clinician's office.³¹ Administrators can also use paper forms, though many find electronic PROMs preferable.³²

²⁸ Charlotte Kingsley & Sanjiv Patel, *Patient-Reported Outcome Measures and Patient-Reported Experience Measures*, 17 BJA EDUC. 137, 137 (2017).

²⁹ NATIONAL QUALITY FORUM, *supra* note 7, at 5 (listing "five categories of PROs"); Manoj Sivan, Shaney Wright, Sarah Hughes, & Melanie Calvert, *Using Condition Specific Patient Reported Outcome Measures for Long COVID*, 376 BMJ o257 (2022).

³⁰ Jill Dawson, Helen Doll, Ray Fitzpatrick, Crispin Jenkinson & Andrew J. Carr, *Routine Use of Patient Reported Outcome Measures in Healthcare Settings*, 340 BMJ 464, 464 (2010).

³¹ DAVID CELLA ET AL., PATIENT-REPORTED OUTCOMES IN PERFORMANCE MEASUREMENT 7 (2015), https://www.ncbi.nlm.nih.gov/books/NBK424378/pdf/Bookshelf_NBK424378.pdf; Rachel C. Sisodia, Jorge A. Rodriguez & Thomas D. Sequist, *Digital Disparities: Lessons Learned from a Patient Reported Outcomes Program during the COVID-19 Pandemic*, 28 J. AM. MED. INFORMATICS ASS'N 2265, 2265 (2021).

³² Jennifer Y. Yu, Talia Goldberg, Nicholas Lao, Brian M. Feldman & Y. Ingrid Goh, *Electronic Forms for Patient Reported Outcome Measures (PROMs) Are an Effective, Time-Efficient, and Cost Minimizing Alternative to Paper Forms*, 19 PEDIATRIC RHEUMATOLOGY 67, 67 (2021).

One example is the following short form sleep survey:³³

ASCQ-Me[®] v2.0 Sleep Impact - Short Form

Sleep Impact Short Form

Please respond to each question or statement by marking one box per row.

| | | Never | Rarely | Sometimes | Often | Always |
|----------------|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| SleepImpactQ2 | In the past 7 days, how often did you stay up most of the night because you could not fall asleep? | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 |
| SleepImpactQ5 | In the past 7 days, how often was it very easy for you to fall asleep? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| SleepImpactQ8 | In the past 7 days, how often did you have a lot of trouble falling asleep | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 |
| SleepImpactQ10 | In the past 7 days, how often did you stay up all night because you could not fall asleep? | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 |
| SleepImpactQ11 | In the past 7 days, how often did you stay up half of the night because you could not fall asleep? | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 |

A second example is the Oxford hip score, which uses twelve questions to evaluate hip pain and function in patients that may need hip replacements.³⁴ Patients are asked to rate different types of hip pain (e.g. nighttime pain, shooting pain) and how it affects various functions, such as walking, climbing stairs, bathing, and shopping and are given five choices for each answer to indicate range of discomfort severity.³⁵ Patients' ratings in response to the individual questions are combined to generate an overall score.³⁶ Thus, in the hip survey, scores in the range of 40-48 indicated that treatment is most likely not needed, and, at the other end of the spectrum, scores in the range of 0-19 indicate the presence of severe arthritis and a likely need for surgery.³⁷

PROMs can systematically collect information that would otherwise be difficult to obtain. For example, PROMs are particularly useful for those treating pain

³³ Health Measures, *ASCQ-Me v2.0 - Sleep Impact Short Form* 10Oct2017, <https://www.healthmeasures.net/search-view-measures?task=Search.search> (last visited Dec. 11, 2022). Reproduced with the permission of the American Institutes for Research, Copyright 2010-2023.

³⁴ *Oxford Hip Score*, http://www.orthopaedicscore.com/scorepages/oxford_hip_score.html (last visited Dec. 11, 2022).

³⁵ *Id.*

³⁶ Dawson et al., *supra* note 30, at 464.

³⁷ *Oxford Hip Score*, *supra* note 34.

because pain cannot be objectively measured.³⁸ Information about patients' symptoms, functionality, and quality of life can also be invaluable in the specialties of oncology,³⁹ cardiology,⁴⁰ neurology,⁴¹ rheumatology,⁴² and more.

In recent draft guidance, the FDA stated that PROMs are the best means of assessing the following:

- A feeling or experience known only to the patient, such as pain, itch, shortness of breath as no one else has direct access to feelings except for the patient
- Any type of functioning or activity that is part of the patients' day-to-day life
- The patients' satisfaction or dissatisfaction with their treatment and/or functioning
- Degree of impact on day-to-day life associated with one or more symptoms.⁴³

PROMs are not a novel concept, and they have been embraced internationally. As early as 1975, Sweden incorporated PROMs into clinical databases that were disease specific.⁴⁴ By 2000 PROMs were used by some U.S. practices, and since 2009, the United Kingdom has required that PROMs be collected for patients that undergo certain elective surgeries.⁴⁵ The International Consortium for Health Outcomes Measurement (ICHOM), founded in 2012, states that its mission is to “unlock the potential of value-based health care by defining global Patient-Centered Outcome Measures ... that really matter to patients for the most relevant medical conditions and by driving adoption and reporting of these measures

³⁸ Michelle M. Holmes, George Lewith, David Newell, Jonathan Field & Felicity L. Bishop, *The Impact of Patient-Reported Outcome Measures in Clinical Practice for Pain: A Systematic Review*, 26 *QUAL. LIFE RES.* 245, 249 (2017).

³⁹ Roxanne E. Jensen et al., *Review of Electronic Patient-Reported Outcomes Systems Used in Cancer Clinical Care*, 10 *J. ONCOL. PRACT.* e215, e215 (2014); Warsame & D'Souza, *supra* note 18, at 2291.

⁴⁰ Jonathan Davis, *Do Patient-Reported Outcome Measures Measure Up? A Qualitative Study to Examine Perceptions and Experiences with Heart Failure PROMs among Diverse, Low-Income Patients*, 6 *J. PATIENT-REPORTED OUTCOMES* 6, 6 (2022).

⁴¹ Olga Damman et al., *Using PROMs during Routine Medical Consultations: The Perspectives of People with Parkinson's Disease and their Health Professionals*, 22 *HEALTH EXPECTATIONS* 939, 939 (2019).

⁴² Brittany R. Lapin et al., *Patient-Reported Experience with Patient-Reported Outcome Measures in Adult Patients Seen in Rheumatology Clinics*, 30 *QUALITY LIFE RES.* 1073, 1073 (2021).

⁴³ U.S. Department of Health and Human Services et al., *Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for Purpose Clinical Outcome Assessments: Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders*, Draft Guidance, June 2022, <https://www.fda.gov/media/159500/download>.

⁴⁴ Fleischmann & Vaughan, *supra* note 13, at 57.

⁴⁵ *Id.*

worldwide.”⁴⁶ To that end, ICHOM focuses on PROMs – outcomes that are reported directly by patients without being interpreted by clinicians.⁴⁷

In 2004, the National Institutes of Health (NIH) launched the Patient Reported Outcomes Measurement Information System (PROMIS).⁴⁸ Researchers used advanced psychometric⁴⁹ techniques to validate existing survey instruments and to create better tools.⁵⁰ The PROMIS website features 649 English surveys relating to anxiety, depression, fatigue, pain, sleep disturbance, physical functioning, satisfaction with participation in social roles, and much more.⁵¹ These are available free of charge to anyone who wishes to access them.⁵² Many experts consider PROMIS to be the gold standard for patient-generated assessments.⁵³ PROMIS aims to standardize PROMs just as blood chemistry outcomes are standardized.⁵⁴ PROMIS measures produce T-scores, which can be defined as “standard scores with a mean of 50 and standard deviation of 10 in a reference population (usually U.S. general population).”⁵⁵ This enables comparison of an individual’s health status to that of the general population, or in some cases, a sub-population of interest (e.g. cancer patients).⁵⁶

⁴⁶ ICHOM, *Frequently Asked Questions*, <https://www.ichom.org/faqs/#:~:text=ICHOM%20was%20founded%20in%202012,and%20the%20Boston%20Consulting%20Group>. (last visited Dec. 11, 2022).

⁴⁷ International Consortium for Health Outcomes Measurement, *Electronic PROMs: What's the Right Solution for Your Organization?* 1 (2014), <https://ichom.org/files/articles/ePROM-White-Paper.pdf>.

⁴⁸ National Institutes of Health, *Patient Reported Outcomes Measurement Information System: Program Snapshot*, <https://commonfund.nih.gov/promis/index> (last reviewed Jan. 29, 2019); Douglas M. Lawson, *PROMIS: a New Tool for the Clinician Scientist*, 55 J. CAN. CHIROP. ASS'N 16, 16 (2011).

⁴⁹ Psychometrics is “the branch of psychology concerned with the quantification and measurement of mental attributes, behavior, performance, and the like, as well as with the design, analysis, and improvement of the tests, questionnaires, and other instruments used in such measurement.” American Psychological Association, *Psychometrics*, APA DICTIONARY PSYCH., <https://dictionary.apa.org/psychometrics> (last visited Dec. 11, 2022).

⁵⁰ Lawson, *supra* note 48, at 16.

⁵¹ *Id.* at 17; Health Measures, *Intro to PROMIS*, <https://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis> (last visited Dec. 11, 2022); Health Measures, *Search and View Measures*, <https://www.healthmeasures.net/search-view-measures> (last visited Dec. 11, 2022).

⁵² Lawson, *supra* note 48, at 16.

⁵³ Jonathan P. Evans, Alexander Smith, Chris Gibbons, Jordi Alonso & Jose M Valderas, *The National Institutes of Health Patient Reported Outcomes Measurement Information System (PROMIS): A View from the UK*, 9 PATIENT RELATED OUTCOME MEASURES 345, 350 (2018).

⁵⁴ *Id.* at 346.

⁵⁵ Nan E. Rothrock, Dagmar Amtmann & Karon F. Cook, *Development and Validation of an Interpretive Guide for PROMIS Scores*, 4 J. PATIENT-REPORTED OUTCOMES 1, 2 (2020).

⁵⁶ Thi Xuan Mai Tran, Jungeun Park, Joonki Lee, Yuh-Seog Jung, Yoonjung Chang & Hyunsoon Cho, *Utility of the Patient-Reported Outcomes Measurement Information System (PROMIS) to Measure Primary Health Outcomes in Cancer Patients: A Systematic Review*, 29 SUPPORTIVE CARE IN CANCER 1723, (2021).

Other PROM tools exist as well. One is the Medicare Health Outcomes Survey (HOS).⁵⁷ The HOS is used in all Medicare Advantage plans in order to gather health status data for purposes of quality improvement, monitoring and rewarding plan performance, and helping participants make informed decisions.⁵⁸ Each year a random sample of participants is surveyed, and the respondents are surveyed again after two years.⁵⁹ An additional tool is Focus on Therapeutic Outcomes (FOTO), which collects self-reported data from patients who underwent outpatient rehabilitation.⁶⁰ FOTO assesses functional status changes in patients by comparing PROMs collected before, during, and after rehabilitation.⁶¹

The extent of PROM use in the United States is unclear. According to one source, in 2016 only one-fifth of hospitals routinely used PROMs.⁶² A 2020 study noted that PROM adoption has been “limited” and that there is a “paucity of information on large-scale systemwide implementations that include diverse specialties and clinical settings.”⁶³

To ease the burden of PROM completion and minimize the number of questions presented to patients, PROMs can exploit computer adaptive technology (CAT).⁶⁴ Sometimes trained through machine learning (a type of artificial intelligence), CAT adapts the questions asked of each patient to the individual's prior responses.⁶⁵ Tailoring questionnaires to the responder's symptoms and circumstances and

⁵⁷ Centers for Medicare & Medicaid Services, *Welcome to the Medicare Health Outcomes Survey (HOS) Website*, <https://www.hosonline.org/> (last modified Oct. 20, 2022).

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ FOTO Patient Outcomes, *Frequently Asked Questions*, <https://fotoinc.com/frequently-asked-questions/> (last visited Dec. 11, 2022).

⁶¹ Center for Medicare and Medicaid Services, *Patient Reported Outcomes Measures*, Sept. 2021, <https://www.cms.gov/files/document/blueprint-patient-reported-outcome-measures.pdf>.

⁶² Jennifer Bresnick, *Why Aren't Hospitals Using Patient-Reported Outcomes Data?*, HEALTH IT ANALYTICS, Aug. 2, 2016, <https://healthitanalytics.com/news/why-arent-hospitals-using-patient-reported-outcomes-data>.

⁶³ Rachel C. Sisodia et al., *Factors Associated with Increased Collection of Patient-Reported Outcomes Within a Large Health Care System*, 3 JAMA NETWORK OPEN e202764 (2020). See also, Dana Gelb Safran & Aparna Higgins, *Getting to The Next Generation of Performance Measures for Value-Based Payment*, HEALTH AFFS. FOREFRONT, Jan. 29, 2019, <https://www.healthaffairs.org/doi/10.1377/forefront.20190128.477681/full/> (“To date, systematic use of PROMs in clinical practice has occurred in only a few settings”).

⁶⁴ Liam T. Kane, Surena Namdari, Otho R. Plummer, Pedro Beredjiklian, Alexander Vaccaro, & Joseph A. Abboud, *Use of Computerized Adaptive Testing to Develop More Concise Patient-Reported Outcome Measures*, 5 JBJS OPEN ACCESS e0052, 1 (2020), https://journals.lww.com/jbjsa/fulltext/2020/03000/use_of_computerized_adaptive_testing_to_develop.8.aspx.

⁶⁵ *Id.* at 3. See also, Conrad Harrison, Bao Sheng Loe, Przemysław Lis, Chris Sidey-Gibbons, *Maximizing the Potential of Patient-Reported Assessments by Using the Open-Source Concerto Platform with Computerized Adaptive Testing and Machine Learning*, 22 J. MED. INTERNET RES. e20950, 2 (2020).

eliminating irrelevant standardized queries can cut completion time by as much as fifty percent.⁶⁶

PROMs should be integrated into patients' electronic health records (EHR) so that clinicians can easily review and maintain documentation concerning patient-reported information.⁶⁷ Institutions can design their own integration mechanisms, can opt for EHR systems that embed PROMs, or can purchase independent commercial products to deploy PROMs.⁶⁸ For example, experts at the University of Minnesota and other colleagues developed the Patient Reporting and Insight System from Minnesota (PRISM).⁶⁹ PRISM enables patients to use a mobile app to fill out questionnaires and then integrates the responses into patients' EHRs.⁷⁰ Integrating PROMs into EHRs, however, can be challenging because of cost, logistics, and technological complexities.⁷¹

B. PROM Benefits

PROMs can assist physicians in making medical decisions.⁷² Based on patients' ratings of their discomfort and other quality of life indicators, doctors may change their course of treatment.⁷³ Some outcomes, such as mortality, infections, and disease recurrence can be measured objectively.⁷⁴ But outcomes such as pain levels

⁶⁶ Scott Morris, Mike Bass, Mirinae Lee, & Richard E Neapolitan, *Advancing the Efficiency and Efficacy of Patient Reported Outcomes with Multivariate Computer Adaptive Testing*, 24 J. AM. MED. INFORM. ASS'N 897, 898 (2017) Harrison et al., *supra* note 65, at 2.

⁶⁷ Marzyeh Amini et al., *Facilitators and Barriers for Implementing Patient-Reported Outcome Measures in Clinical Care: An Academic Center's Initial Experience*, 125 HEALTH POL'Y 1247, 1254 (2021); Heather Taffet Gold et al., *Implementation and Early Adaptation of Patient-Reported Outcome Measures into an Electronic Health Record: A Technical Report*, 26 HEALTH INFORMATICS J. 129, 130 (2020); NATIONAL QUALITY FORUM, *supra* note 7, at 21-22; Josef Stehlik et al., *Implementation of Real-Time Assessment of Patient-Reported Outcomes in a Heart Failure Clinic: A Feasibility Study*, 23 J. CARDIAC FAILURE 813, 815 (2017).

⁶⁸ Judith F. Baumhauer, Christopher Dasilva, David Mitten, Paul Rubery & Michael Rotondo, *The Cost of Patient-Reported Outcomes in Medicine*, NEJM CATALYST, Jan. 25, 2018, <https://proms.waitematadhb.govt.nz/assets/Uploads/The-Cost-of-PROMs.pdf>, at 2.

⁶⁹ University of Minnesota, PRISM, [https://healthinformatics.umn.edu/research/research-projects/prism#:~:text=PRISM%2C%20\(Patient%20Reporting%20and%20Insight,outside%20of%20the%20clinical%20setting](https://healthinformatics.umn.edu/research/research-projects/prism#:~:text=PRISM%2C%20(Patient%20Reporting%20and%20Insight,outside%20of%20the%20clinical%20setting). (last visited Dec. 11, 2022).

⁷⁰ *Id.*

⁷¹ Liam H. Wong & James E. Meeker, *The Promise of Computer Adaptive Testing in Collection of Orthopedic Outcomes: An Evaluation of PROMIS Utilization*, 6 J. PATIENT-REPORTED OUTCOMES 1, 12 (2022).

⁷² Holmes et al., *supra* note 38 at 252.

⁷³ Susan J. Bartlett et al., *Patient-Reported Outcomes in RA Care Improve Patient Communication, Decision-Making, Satisfaction and Confidence: Qualitative Results*, 59 RHEUMATOLOGY 1662, 1667 (2020) ("physicians indicated that reviewing PRO results influenced decisions to change or adjust RA [rheumatoid arthritis] treatment in 20% of encounters").

⁷⁴ Rachel Morley & Tristan Leech, *Optimal Assessment Tools in Assessing Breast Surgery: Patient Reported Outcome Measures (PROMs) vs. Objective Measures*, 8 GLAND SURG. 416, 416 (2019).

and psychological wellbeing cannot be objectively assessed, and thus PROMs can complement objective measures and provide valuable insights about patients.⁷⁵

Ideally, physicians should be able to gather comprehensive information about patients' perceptions of their health status by questioning them extensively during office visits, but sadly, that is often not possible in practice. Contemporary physicians are generally pressed for time and are often pressured by employers to limit the duration of visits in order to increase patient volume and profits.⁷⁶ The average primary care visit, for instance, lasts only fifteen to twenty minutes.⁷⁷ Therefore, PROMs may be the only way for clinicians to collect in-depth information about patients' quality of life.

PROMs enable physicians to focus on symptoms, side effects, and outcomes that matter most to patients.⁷⁸ To illustrate, a prostate cancer patient may care deeply not only about survival, but also about impotence and incontinence after treatment.⁷⁹ If doctors collect PROMs about these complications, they will be better equipped to discuss them with patients and to tailor treatment recommendations to patients' concerns.

In some cases, PROMs may save costs.⁸⁰ One study found that careful surveillance of lung cancer patients using PROMs reduced the need for follow-up clinical visits and imaging.⁸¹ In other cases, patients with knee, hip, or back pain whose PROMs reveal that they are high functioning and that their pain is tolerable could be spared expensive, unnecessary, and sometimes risky surgeries.⁸²

⁷⁵ *Id.*; Paul G. Kluetz et al., *Informing the Tolerability of Cancer Treatments Using Patient-Reported Outcome Measures: Summary of an FDA and Critical Path Institute Workshop*, 21 VALUE IN HEALTH 742, 745 (2018) (“clinician reporting of symptomatic adverse events and patient reporting of symptomatic adverse events are complementary”); Walter F. Stewart et al., *Combining Patient Reported Outcomes and EHR Data to Understand Population Level Treatment Needs: Correcting for Selection Bias in the Migraine Signature Study*, 5 J. PATIENT-REPORTED OUTCOMES 132, 141 (2021).

⁷⁶ Sharona Hoffman, *Healing the Healers: Legal Remedies for Physician Burnout*, 18 YALE J. HEALTH, POL’Y, L. & ETHICS 56, 87-92 (2018) (discussing physicians’ inability to spend adequate time with patients).

⁷⁷ *Id.* at 88.

⁷⁸ Youssef Ben Bouazza et al., *Patient-Reported Outcome Measures (PROMs) in the Management of Lung Cancer: A Systematic Review*, 113 LUNG CANCER 140, 146 (2017) (discussing the benefits of PROMs).

⁷⁹ Health Catalyst Editors, *Unlocking the Power of Patient-Reported Outcome Measures (PROMs)*, HEALTH CATALYST, Feb. 26, 2019, <https://www.healthcatalyst.com/insights/unlocking-the-power-of-patient-reported-outcome-measures-proms/>.

⁸⁰ Thibaut Lizée et al., *Cost-Effectiveness of Web-Based Patient-Reported Outcome Surveillance in Patients with Lung Cancer*, 14 J. THORACIC ONCOLOGY 1012, 1012-13 (2019).

⁸¹ *Id.*

⁸² Safran & Higgins, *supra* note 63. See also *infra* notes 297-299 and accompanying text.

Since PROMs come directly from patients, they are free of any bias that might be introduced by clinicians interpreting what patients tell them.⁸³ At least in some instances, therefore, they can provide better data than physicians' descriptions of symptoms.⁸⁴

PROMs can potentially improve the physician-patient relationship by enhancing communication and patient engagement.⁸⁵ PROM questionnaires can help patients remember their symptoms and drug side effects.⁸⁶ They can induce patients to think more deeply about their health status and to enhance their understanding of their medical conditions.⁸⁷ PROMs can also make patients feel empowered to discuss concerns with their physicians because clinicians have solicited their views through the questionnaires.⁸⁸ PROMs can help patients articulate their concerns and raise problems they may have otherwise failed to report.⁸⁹ They can therefore facilitate conversations with clinicians, enhance shared decision making, and increase patients' satisfaction with their care.⁹⁰

One study focused on PROM use for rheumatology patients at the Cleveland Clinic.⁹¹ It revealed that seventy-eight percent agreed or strongly agreed that answering PROMs enhanced communication with their physicians, and seventy percent agreed or strongly agreed that doing so made them feel that they had more control over their own care.⁹²

According to some estimates, oncologists miss symptoms, impaired functioning, and adverse effects of treatment fifty to seventy-four percent of the time.⁹³ Physician awareness and response to these matters can generate dramatic benefits for patients. In one study, monitoring patient-reported outcomes increased

⁸³ Warsame & D'Souza, *supra* note 18, at 2291.

⁸⁴ *Id.* But see *infra* Part I.C (discussing PROM shortcomings and concerns).

⁸⁵ Holmes et al., *supra* note 38 at 252; Danielle C. Lavalley et al., *Incorporating Patient-Reported Outcomes into Health Care to Engage Patients and Enhance Care*, 35 HEALTH AFFAIRS 575, 575 (2016).

⁸⁶ Lapin et al., *supra* note 42, at 1076-7.

⁸⁷ Joanne Greenhalgh et al., *supra* note 15, at 63.

⁸⁸ *Id.*; Bartlett et al., *supra* note 73, at 1668.

⁸⁹ Warsame & D'Souza, *supra* note 18, at 2297-8.

⁹⁰ Lapin et al., *supra* note 42, at 1076-7. But see Part I.C.2.a (discussing patients' concerns about PROMs).

⁹¹ *Id.* at 1074.

⁹² *Id.* at 1076.

⁹³ Warsame & D'Souza, *supra* note 18, at 2297. See also, Massimo Di Maio et al., *Symptomatic Toxicities Experienced During Anticancer Treatment: Agreement Between Patient and Physician Reporting in Three Randomized Trials*, 33 J. CLIN. ONCOLOGY 910, 914 (2015) (concluding that "subjective toxicities associated with anticancer treatments are at high risk of under-reporting by physicians" and recommending that patient-reported data be incorporated "into toxicity reports in clinical trials").

the survival of individuals with metastatic cancer by 5.2 months.⁹⁴ Participants in this study were randomly assigned either to receive usual care or to answer questions concerning twelve common symptoms via a web-based platform at and between office visits.⁹⁵ Reports of severe or worsening symptoms would trigger emails to clinical nurses, and oncologists received summaries of patients' symptom histories at each appointment.⁹⁶

PROMs can also provide invaluable information concerning emerging diseases, such as COVID-19. A 2020 study, for example, showed that seventy-six percent of patients who had been hospitalized for COVID-19 continued to have abnormal PROMs three months after the onset of their initial symptoms.⁹⁷ A third of these individuals reported "at least moderate impairment in major dimensions of quality of life."⁹⁸ Clinicians could learn a great deal about long COVID from such responses.

Public access to anonymized or summarized PROMs could enable patients to make more educated choices with respect to clinicians, medical facilities, and therapeutic options and to have realistic expectations about treatments and recovery.⁹⁹ Individuals could select providers based on patient accounts of their post-treatment quality of life, such as whether they suffered incontinence or impotence after prostate surgery.¹⁰⁰ Patients could also gain insight concerning others' experiences during treatment and recovery, so that they know what to anticipate and can perhaps be less anxious or concerned.¹⁰¹

Insurers may use PROMs to determine which health care providers and services to include in their networks.¹⁰² Insurers may also use PROMs to create profiles of high-risk patients that will incur high costs and to develop programs and interventions that might improve their health.¹⁰³

⁹⁴ Ethan Basch & Allison M. Beal, *Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment*, 318 JAMA 197, 198 (2017) ("Median overall survival was 31.2 months (95% CI, 24.5-39.6) in the PRO group and 26.0 months (95% CI, 22.1-30.9) in the usual care group.").

⁹⁵ *Id.* at 197.

⁹⁶ *Id.*

⁹⁷ Alyson W. Wong, Aditi S. Shah, James C. Johnston, Christopher Carlsten & Christopher J. Ryerson, *Patient-Reported Outcome Measures after COVID-19: A Prospective Cohort Study*, 56 EUR. RESPIR. J. 2003276 (2020), <https://erj.ersjournals.com/content/56/5/2003276>.

⁹⁸ *Id.*

⁹⁹ Health Catalyst Editors, *supra* note 79; William B. Weeks & James N. Weinstein, *Patient-Reported Data Can Help People Make Better Health Care Choices*, HARV. BUS. REV., Sept.21, 2015, <https://hbr.org/2015/09/patient-reported-data-can-help-people-make-better-health-care-choices>.

¹⁰⁰ Health Catalyst Editors, *supra* note 79.

¹⁰¹ *Id.*

¹⁰² Neubert et al., *supra* note 14, at 7.

¹⁰³ *Id.* at 7-8.

Quality improvement initiatives can benefit from PROMs as well.¹⁰⁴ Patients' own perceptions regarding treatment outcomes and the care they receive are an important component of assessing the performance of health care providers and identifying areas for improvement.¹⁰⁵

C. PROM Shortcomings and Concerns

Despite their many potential benefits, PROMs face strong critics who voice significant concerns about the tools and their implementation.¹⁰⁶ This Part analyzes data quality and administrative challenges that constitute barriers to PROM implementation in both clinical and other contexts.

1. Data Quality

A large number of defects can taint data quality. This section analyzes the primary sources of data quality problems.

a. Reliability, Responsiveness, and Validity

To be useful, PROMs must be reliable, responsive, and valid.¹⁰⁷ Not all PROMs are of equal quality.¹⁰⁸

Reliability means the degree to which a measure is internally consistent and reproducible.¹⁰⁹ Internal consistency refers to “correlation between different items in the measure.”¹¹⁰ If a survey is internally consistent, responders will answer items that test the same value similarly.¹¹¹ For example, if the survey tests optimism, optimistic respondents will give high ratings to optimism indicators and low ratings to pessimism indicators throughout.¹¹²

¹⁰⁴ A. Costal Tirado et al., *Using Patient-Reported Outcome Measures for Quality Improvement in Clinical Genetics: an Exploratory Study*, 26 J. GENET. COUNSEL. 1017, 1025 (2017).

¹⁰⁵ *Id.* at 1027; Canadian Institute for Health Information, *Patient-reported outcome measures (PROMs)*, <https://www.cihi.ca/en/patient-reported-outcome-measures-proms> (last visited Dec. 11, 2022).

¹⁰⁶ See e.g. CELLA ET AL., *supra* note 31, at 36.

¹⁰⁷ Marlene H. Frost, Bryce Reeve, Astra M. Liepa, Joseph W. Stauffer & Ron D. Hays, *What Is Sufficient Evidence for the Reliability and Validity of Patient-Reported Outcome Measures?*, 10 VALUE IN HEALTH S94, S94 (2007); Angela Ju & Allison Tong, *Considerations and Challenges in Selecting Patient-Reported Outcome Measures for Clinical Trials in Nephrology*, 12 CLIN. J. AM. SOC'Y NEPHROL. 1882, 1883-84 (2017).

¹⁰⁸ Laith Alrubaiy, Hayley A. Hutchings & John G. Williams, *Assessing Patient Reported Outcome Measures: A Practical Guide for Gastroenterologists*, 2 UNITED EUROPEAN GASTROENTEROLOGY J. 463, 463 (2014) (“Not all PROM instruments currently used in research and clinical practice in gastroenterology have gone through a rigorous development methodology.”).

¹⁰⁹ Ju & Tong, *supra* note 107, at 1883.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² Fiona Middleton, *The 4 Types of Reliability | Definitions, Examples, Methods*, SCRIBBR, July 16, 2021, <https://www.scribbr.com/methodology/types-of-reliability/>.

Reproducibility refers to a tool's ability to generate the same result when it is used multiple times in similar circumstances.¹¹³ Thus, if a person takes a survey repeatedly without any change in health status, the individual's responses should be very similar.¹¹⁴

Responsiveness is a measure's ability to discern outcome changes over time.¹¹⁵ This includes both changes in health status and changes in response to medical interventions.¹¹⁶ Responsiveness may be limited by a variety of factors, such as questions that offer too few answer choices and do not enable patients to indicate subtle alterations in their condition.¹¹⁷ Similarly, surveys that are administered too frequently may not give patients time to note meaningful differences in how they feel.

Validity is the extent to which a measure actually assesses what it claims to evaluate.¹¹⁸ This attribute can further be broken down into several categories. Criterion validity is the degree to which a measure relates to a gold standard, if one exists.¹¹⁹ Content validity refers to a measure's ability to cover all dimension that are important to the condition in question. Construct validity is the degree to which the measure evaluates the intended outcome (e.g. fatigue).¹²⁰ External validity has to do with whether identified causal relationships can be generalized to other patients and circumstances.¹²¹ Internal validity is the extent to which observed results truly represent a causal relationship.¹²² Other forms of validity have also been recognized.¹²³

Experts use special techniques to validate survey instruments.¹²⁴ For instance, Validity can sometimes be measured by comparing PROM scores to other related

¹¹³ Alrubaiy et al., *supra* note 108, at 465 (“The principle of reliability is that applying the PROM in different occasions or by different observers produces similar results”); Ju & Tong, *supra* note 107, at 1883.

¹¹⁴ Ju & Tong, *supra* note 107, at 1883 (“Reproducibility is assessed by examining the degree of agreement between scores on the measure at first assessment and when reassessed”); DAVID CELLA ET AL., *supra* note 31, at 39.

¹¹⁵ Ju & Tong, *supra* note 107, at 1884.

¹¹⁶ CELLA ET AL., *supra* note 31, at 40.

¹¹⁷ *Id.* at 48.

¹¹⁸ Ju & Tong, *supra* note 107, at 1884.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 1883-84.

¹²¹ Allan Steckler & Kenneth R. McLeroy, *The Importance of External Validity*, 98 AM. J. PUB. HEALTH 9 (2008).

¹²² *Id.*; Cecilia Maria Patino & Juliana Carvalho Ferreira, *Internal and External Validity: Can You Apply Research Study Results to Your Patients?*, 44 J. BRAS. PNEUMOL. 183, 183 (2018).

¹²³ Ju & Tong, *supra* note 107, at 1883-84; Godfred O. Boateng, Torsten B. Neilands, Edward A. Frongillo, Hugo R. Melgar-Quinonez & Sera L. Young, *Best Practices for Developing and Validating Scales for Health, Social, and Behavioral Research: A Primer*, FRONT. PUBLIC HEALTH, June 11, 2018, pp. 13-14, <https://www.frontiersin.org/articles/10.3389/fpubh.2018.00149/full>,

¹²⁴ Boateng et al., *supra* note 123, at 13.

variables, such as clinical outcomes noted in EHRs.¹²⁵ To illustrate, one study focused on sleep and compared self-reports to objective measures of sleep.¹²⁶ It found that on average, participants slept six hours but reported sleeping 0.8 hours longer than they did. Analysts who are aware of such discrepancies might determine that a sleep PROM is not valid or adjust for the discrepancies when analyzing data.

Not all PROMs are validated with equal rigor.¹²⁷ Furthermore, if a PROM is used for different purposes (e.g. clinical care, research, performance measures) or multiple populations (e.g. older patients, people with different underlying diseases), it may require different validations.¹²⁸

b. Response Shift and Response Bias

A phenomenon known as response shift can impact PROMs' integrity as well.¹²⁹ Response shift occurs because of a change in a responder's perspective, for example, because of an alteration in the individual's internal measurement standards or values.¹³⁰ Therefore, response variations over time may reflect differences in a patient's attitude rather than health status.

Response bias is yet another barrier. At times, individuals' responses aim to reflect what they think the questioner wants to hear or what will impress the questioner rather than to be completely truthful.¹³¹ This bias may also be called "social desirability bias."¹³² In the voting arena, for example, researchers have found that individuals untruthfully claim to have voted when they have not gone to the polls because they believe that is the correct and admirable answer to provide.¹³³ Similarly, some physicians feel that patients' answers are influenced by a desire to

¹²⁵ Ju & Tong, *supra* note 107, at 1884.

¹²⁶ Diane S. Lauderdale, Kristen L. Knutson, Lijing L. Yan, Kiang Liu, and Paul J. Rathouz, *Sleep Duration: How Well Do Self-Reports Reflect Objective Measures? The CARDIA Sleep Study*, 19 EPIDEMIOLOGY 838, 838 (2008).

¹²⁷ Kate Churruca et al., *Patient-Reported Outcome Measures (PROMs): A Review of Generic and Condition-Specific Measures and a Discussion of Trends and Issues*, 24 HEALTH EXPECTATIONS 1015, 1021 (2021); Ju & Tong, *supra* note 136, at 1882.

¹²⁸ Churruca et al., *supra* note 127, at 1021; John T. Farrar, *Advances in Clinical Research Methodology for Pain Clinical Trials*, 6 NATURE MED. 1284, 1289 (2010) ("careful consideration should be given to each particular use, as subtle changes in the questions used or the population of interest can affect the results").

¹²⁹ CELLA ET AL., *supra* note 31, at 33.

¹³⁰ *Id.*

¹³¹ Allyson L. Holbrook & Jon A. Krosnick, *Social Desirability Bias in Voter Turnout Reports: Tests Using the Item Count Technique*, 74 PUBLIC OPINION QUARTERLY 37, 37 (2010); Grace M. Turner, Ian Litchfield, Sam Finnikin, Olalekan Lee Aiyegbusi & Melanie Calvert, *General Practitioners' Views on Use of Patient Reported Outcome Measures in Primary Care: A Cross-Sectional Survey and Qualitative Study*, 21 BMC FAMILY PRACTICE 14, 20 (2020).

¹³² Holbrook & Krosnick, *supra* note 131, at 37.

¹³³ *Id.*

please the physician or gain some benefit by overstating or understating their symptoms.¹³⁴

c. PROM Selection

Determining which PROMs will best fit patients' and clinicians' needs is a challenging task.¹³⁵ Given the breadth of choices, it is difficult to identify PROMs that are the most appropriate, valid, and illuminating for each condition and practice.¹³⁶

There is no consensus as to PROM choices for particular conditions and no standardized PROM sets that are endorsed by professional organizations.¹³⁷ Thus, researchers continue to explore and compare PROMs. The NIH states that its PROMIS project has generated over four-hundred publications.¹³⁸ For example, one study compared PROMIS general health questionnaires for individuals who underwent carpal tunnel hand surgery with “the performance of region- and condition-specific PROMs such as the Michigan Hand Questionnaire (MHQ) and the Boston Carpal Tunnel Questionnaire (BCTQ).”¹³⁹ It found that the PROMIS physical function PROMs were not useful for evaluating these surgical patients but the upper extremity and pain interference domains were.¹⁴⁰ Some experts recommend use of a combination of generic and condition-specific PROMs in order to obtain the most meaningful data.¹⁴¹

d. Missing Data and PROM Timing

Some health care providers resist PROMs adoption because of concern about the accuracy and comprehensiveness of the data.¹⁴² While patients can be asked to

¹³⁴ Turner et al., *supra* note 131, at 7.

¹³⁵ Churrua et al., *supra* note 127, at 1021; San Keller, Sydney Dy, Renee Wilson, Vadim Dukhanin, Claire Snyder, & Albert Wu, *Selecting Patient-Reported Outcome Measures to Contribute to Primary Care Performance Measurement: A Mixed Methods Approach*, 35 J. GEN. INTERNAL MED. 2687, 2688 (2020); Caroline B. Terwee et al., *Common Patient-Reported Outcomes across ICHOM Standard Sets: The Potential Contribution of PROMIS®*, 21 BMC MED. INFORMATICS & DECISION MAKING, Article number: 259, 259 (2021).

¹³⁶ Ju & Tong, *supra* note 107, at 1882 (“selecting a robust and validated PROM from the plethora of available measures is challenging”); Tran et al., *supra* note 56, at 1724 (“The selection of a meaningful PRO instrument that provides accurate assessment and, at the same time, maximizes feasibility for clinical use is, thus, a challenge.”).

¹³⁷ Massachusetts Medical Society, *supra* note 18, at 9.

¹³⁸ National Institutes of Health, *Patient-Reported Outcome Measurement Information System (PROMIS): Program Snapshot*, <https://commonfund.nih.gov/promis/index> (last reviewed Jan. 29, 2019).

¹³⁹ David N. Bernstein, Jeff R. Houck, Bilal Mahmood & Warren C. Hammert, *Responsiveness of the PROMIS and its Concurrent Validity with Other Region- and Condition-specific PROMs in Patients Undergoing Carpal Tunnel Release*, 477 CLIN. ORTHOP. RELAT. RES. 2544, 2544 (2019).

¹⁴⁰ *Id.* at 2545.

¹⁴¹ CELLA ET AL., *supra* note 31, at 48.

¹⁴² Ryan P. Jacobson, Daniel Kang & Jeff Houck, *Can Patient-Reported Outcomes Measurement Information System® (PROMIS) Measures Accurately Enhance Understanding of Acceptable Symptoms and Functioning in Primary Care?*, 4 J PATIENT-REPORTED OUTCOMES 1, 2 (2020).

complete PROMs, they are not forced to do so or to answer every question in the survey.

Several studies highlight the problem of missing data.¹⁴³ Some respondents may skip questions or stop answering surveys prematurely because they are fatigued, confused, bored with the activity, or are called into their appointment and thus run out of time.¹⁴⁴ In addition, some patients may not respond to surveys at all, and response rates may depend on how aggressively health care providers encourage patients to answer PROMs.¹⁴⁵

Response rate discrepancies can skew results in research studies or oversight initiatives that compare health care providers. Treatment outcomes of those who diligently pursue PROM responses, including from very sick patients, may look worse than outcomes from entities that are more passive in encouraging patients to fill out PROMs.¹⁴⁶ At the same time, resource-poor organizations may not have the funds to implement PROMs and may not be included in clinical trials that solicit PROMs.¹⁴⁷ If that is the case, little to no data would be gathered from important segments of the population that suffer socioeconomic disadvantages.¹⁴⁸ The results of such research would be of questionable external validity and likely would not be generalizable to excluded populations.¹⁴⁹

Furthermore, vital details may be missing from PROM surveys. To illustrate, hip replacement surgery may not be as helpful for individuals who have other conditions that affect mobility, but surveys may not ask patients about these comorbidities.¹⁵⁰ Cultural background may also influence how people answer PROMs, causing some people to misinterpret questions or be reluctant to respond negatively about their health or treatment.¹⁵¹

¹⁴³ See Fatima Al Sayah, Markus Lahtinen, Gouke J. Bonsel, Arto Ohinmaa & Jeffrey A. Johnson, *A Multi-Level Approach for the Use of Routinely Collected Patient-Reported Outcome Measures (PROMs Data in Healthcare Systems)*, 5(Suppl 2) J. PATIENT REP. OUTCOMES 98, 5 (2021); Olawale F. Ayilara, Lisa Zhang, Tolulope T. Sajobi, Richard Sawatzky, Erik Bohm & Lisa M. Lix, *Impact of Missing Data on Bias and Precision when Estimating Change in Patient-Reported Outcomes from a Clinical Registry*, 17 HEALTH & QUALITY LIFE OUTCOMES 106, 107 (2019); Basch & Beal, *supra* note 94, at 503.

¹⁴⁴ See *infra* notes 171-176 and accompanying text (discussing survey fatigue).

¹⁴⁵ See Basch & Beal, *supra* note 94, at 503.

¹⁴⁶ See Basch & Beal, *supra* note 94, at 503.

¹⁴⁷ See *infra* notes 183-184 and accompanying text (discussing implementation costs).

¹⁴⁸ Rivera et al., *supra* note 8, at 1911 (“PRO research may not reflect the perspectives of underserved groups such as older individuals, socioeconomically disadvantaged populations, and racial and ethnic minority groups which could threaten the scientific validity of results”).

¹⁴⁹ *Id.* See also Sharona Hoffman & Andy Podgurski, *The Use and Misuse of Biomedical Data: Is Bigger Really Better?*, 39 AM. J. L. MED 497, 521-23 (2013) (discussing selection bias, which occurs “when the subset of individuals studied is not representative of the patient population of interest”). See *supra* note 121 and accompanying text for discussion of external validity.

¹⁵⁰ Dawson et al., *supra* note 30, at 466.

¹⁵¹ CELLA ET AL., *supra* note 31, at 39.

A further complication is that multiple choice questions, which are the format for many PROMs, may not capture all necessary information. A study relating to pain concluded that narratives descriptions of pain provided the best insight into patients' experiences.¹⁵² If analysts do not collect appropriate auxiliary data about responders, they may not be able to contextualize and interpret PROM results correctly.¹⁵³

Using PROMs for purposes other than clinical care (such as research or FDA oversight) can be problematic for additional reasons as well. Survey responders may be a self-selected group that differs from non-responders in important ways, including health status, socioeconomic status, or other attributes.¹⁵⁴ Individuals with low literacy or with language barriers are unlikely to complete PROMs.¹⁵⁵ Individuals with cognitive decline or other intellectual or physical disabilities may also be unable to complete PROMs.¹⁵⁶ If many potential participants face these barriers, PROM responders would not be representative of the relevant patient population at large (e.g. all patients with heart failure), and there will be significant gaps in the data collected.¹⁵⁷

Comparison and assessment of treatment outcomes may also be hindered by the timing of PROM collection.¹⁵⁸ If different patients submit PROMs at different intervals following a medical intervention, they will not provide information that is easy to synthesize.¹⁵⁹ Determining the appropriate point at which to solicit PROMs is itself complicated.¹⁶⁰ Collecting PROMs too soon after an intervention may not provide complete data as to its impact, but collecting them after significant time has

¹⁵² Timothy H. Wideman, Robert R. Edwards, David M. Walton, Marc O. Martel, Anne Hudon & David A. Seminowicz, *The Multimodal Assessment Model of Pain: A Novel Framework for Further Integrating the Subjective Pain Experience within Research and Practice*, 35 CLIN. J. PAIN 212, 215 (2019).

¹⁵³ Dawson et al., *supra* note 30, at 466.

¹⁵⁴ Dawson et al., *supra* note 30, at 466.

¹⁵⁵ CELLA ET AL., *supra* note 31, at 28-31.

¹⁵⁶ *Id.* at 31; Jessica M. Kramer & Ariel Schwartz, *Reducing Barriers to Patient-Reported Outcome Measures for People with Cognitive Impairments*, 98 ARCHIVES PHYSICAL MED. & REHABILITATION 1705, 1705 (2017); Hahn Nguyen, Phyllis Butow, Haryana Dhillon & Puma Sundaresan, *A Review of the Barriers to Using Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs) in Routine Cancer Care*, 68 J. MED. RADIAT. SCI. 186, 188 (2021).

¹⁵⁷ *Id.*; Walter F. Stewart et al., *supra* note 75, at 140 (2021) (discussing significant differences between respondents and non-respondents that resulted in differences between respondents and the total source population).

¹⁵⁸ Al Sayah et al., *supra* note 143, at 5 (referring to “varying time points of PROM(s) measurement”); Dawson et al., *supra* note 30, at 466 (“Follow-up times should be the same for all patients in relation to the intervention or other key event”).

¹⁵⁹ Dawson et al., *supra* note 30, at 466.

¹⁶⁰ Nick Black, *Patient Reported Outcome Measures Could Help Transform Healthcare*, 346 BMJ 1167, 1169 (2013).

passed makes it difficult to attribute all reported phenomena to the intervention at issue rather than to other intervening factors.¹⁶¹

e. Interpretability

In order to be useful, PROMs data must be available in formats that are accessible and easy to interpret.¹⁶² In many cases, clinicians do not know how to interpret PROMs and integrate them into patient care.¹⁶³ Clinicians must easily be able to determine what changes in PROM scores mean and whether they indicate significant improvement or deterioration in a patient's condition.¹⁶⁴ As the National Quality Forum noted, "PROM scores and results must be integrated and viewed as actionable values upon a quick glance to successfully be incorporated into the clinical treatment plan."¹⁶⁵ Ideally, patients should also be able to view and understand their PROMs.¹⁶⁶ Raw scores alone, without explanation and contextualization, might be of little value to providers and the patients they serve.¹⁶⁷

2. Administrative Challenges

Implementing a PROMs program can be challenging, even with high-quality PROMs. PROMs might face resistance from both patients and providers, as detailed below.

a. Patient Concerns

A variety of obstacles may hinder PROM completion. Patients may find that PROMs are collected through a platform that is inaccessible or difficult to use or that questions are hard to understand.¹⁶⁸

If patients are not given tablet computers at the clinician's office or are not able to seek assistance while using them, they may ignore requests for PROMs.¹⁶⁹ In one instance, Mass General Brigham found that when it discontinued tablet use because of COVID-19, significant racial disparities in the rate of PROM completion developed.¹⁷⁰ Patients identifying as Black provided PROMs at half the rate of White patients, and self-identifying Hispanics essentially did not fill them

¹⁶¹ *Id.*

¹⁶² See Basch & Beal, *supra* note 94, at 503; NATIONAL QUALITY FORUM, *supra* note 7, at 20.

¹⁶³ Nguyen et al., *supra* note 156, at 191.

¹⁶⁴ NATIONAL QUALITY FORUM, *supra* note 7, at 20.

¹⁶⁵ *Id.*, Stehlik et al., *supra* note 67, at 815 ("It will also be important to determine the best approaches with which to share the results with the patients so that they understand the meaning of the scores and remain engaged in the process of serial PRO assessment").

¹⁶⁶ NATIONAL QUALITY FORUM, *supra* note 7, at 20.

¹⁶⁷ *Id.* ("Real-time information and interpretation must be available to accompany PROM scores.")

¹⁶⁸ Stine Thestrup Hansen, Mette Kjerholt, Sarah Friis Christensen, John Brodersen & Bibi Hølge-Hazelton, *User Experiences on Implementation of Patient Reported Outcome Measures (PROMs) in a Haematological Outpatient Clinic*, 4 J. PATIENT-REPORTED OUTCOMES 87, 96 (2020); Massachusetts Medical Society, *supra* note 18, at 6-7.

¹⁶⁹ Massachusetts Medical Society, *supra* note 18, at 6-7.

¹⁷⁰ Sisodia, Rodriguez & Sequist, *supra* note 31, at 2266.

out at all, perhaps because of problems accessing computers and the Internet at home.¹⁷¹ On the other hand, patients with certain disabilities such as Parkinson's disease may not have the dexterity to work with tablet computers in the clinic and might prefer to use their home computers.¹⁷² Others with learning disabilities, cognitive decline, or mental health conditions may not be able to complete PROMs on their own at all.¹⁷³

Survey fatigue is an additional concern.¹⁷⁴ If patients are inundated with requests for PROMs, they may fill out questionnaires as quickly as possible without adequate thought, respond to only some of the queries, or ignore surveys altogether.¹⁷⁵ According to one source, respondents generally stop answering questions after thirty queries.¹⁷⁶ Thus, survey fatigue could contribute to low response rates, missing data, and poor data quality in PROMs.¹⁷⁷ Note that in the research context, however, participants will have different expectations and may be willing to fill out longer PROMs.¹⁷⁸

b. Health Care Provider Concerns

Although PROMS can provide valuable information to health care providers,¹⁷⁹ clinicians and staff members may find PROMs to be burdensome and unwelcome additions to their workloads.¹⁸⁰ Burnout among physicians and other health care providers has received increasing attention in recent years.¹⁸¹ Already overstretched providers might feel that the added tasks of processing and reviewing PROMs and responding to patient-reported concerns will be unmanageable for them.¹⁸²

¹⁷¹ *Id.*

¹⁷² CELLA ET AL., *supra* note 31, at 31 (discussing functional abilities and PROMs completion).

¹⁷³ Nguyen et al., *supra* note 156, at 188.

¹⁷⁴ Massachusetts Medical Society, *supra* note 18, at 10.

¹⁷⁵ Vikas N. O'Reilly-Shah, *Factors Influencing Healthcare Provider Respondent Fatigue Answering a Globally Administered In-App Survey*, 5 PEERJ e3785, 2 (2017) ("Respondent fatigue, also known as survey fatigue, is a common problem in the collection of survey data.").

¹⁷⁶ Health Catalyst Editors, *supra* note 79.

¹⁷⁷ Rosaline de Koning et al., *Survey Fatigue During the COVID-19 Pandemic: An Analysis of Neurosurgery Survey Response Rates*, 8 FRONT. SURG. 1, 2, August 12, 2021, <https://www.frontiersin.org/articles/10.3389/fsurg.2021.690680/full>.

¹⁷⁸ CELLA ET AL., *supra* note 31, at 42.

¹⁷⁹ See *supra* notes 72-75 and accompanying text.

¹⁸⁰ Massachusetts Medical Society, *supra* note 18, at 7.

¹⁸¹ Hoffman, *supra* note 76, at 56.

¹⁸² Hansen et al., *supra* note 168, at 96 ("nurses in this study did not use the PROM data and explained that lack of time required a focus on mandatory tasks related to treatment, control and documentation"); Health Catalyst Editors, *supra* note 79 ("it can be difficult to know how to push past the landscape of "I can't do one more thing" when it comes to clinician buy-in"); Massachusetts Medical Society, *supra* note 18, at 7.

The cost of implementation is another concern.¹⁸³ Institutions that adopt PROMs need information technology experts, personnel to maintain the program, and equipment such as tablet computers.¹⁸⁴

While PROMs can improve the physician-patient relationship by focusing doctors' attention on patient concerns, there is also a risk that they will further diminish the time physicians spend face-to-face with patients.¹⁸⁵ If patients are asked to complete PROMs during their appointments, they may have less time to speak with clinicians than they would otherwise.¹⁸⁶

Furthermore, health care employers might require doctors to review PROMs online to obtain data about patients' progress and complaints and then reduce the length of already rushed office visits.¹⁸⁷ Many health care organizations pressure physicians to see more patients and generate more income,¹⁸⁸ and they may consider PROMs a means to further those goals.

II.

CLINICAL USE OF PROMS: PRIVACY AND MALPRACTICE IMPLICATIONS

Health care providers should recognize both the benefits and the shortcomings of PROMs when considering their implementation.¹⁸⁹ In addition, clinical use of PROMs raises important legal questions. This Part provides an overview of two vital issues: privacy and malpractice concerns.

A. Privacy

Patients who complete PROMs may be concerned about the privacy of the information they provide.¹⁹⁰ PROM surveys often ask patients to disclose information about their pain, ability to function, depression, anxiety, sexual satisfaction, and other sensitive matters.¹⁹¹ Once PROMs are completed, they are

¹⁸³ See generally, Baumhauer et al., *supra* note 68.

¹⁸⁴ Massachusetts Medical Society, *supra* note 18, at 8 (discussing implementation costs and barriers to PROM adoption).

¹⁸⁵ *Id.* at 9.

¹⁸⁶ Evelyn Sharples et al., *A Qualitative Exploration of Attitudes Towards the Use of Outcome Measures in Child and Adolescent Mental Health Services*, 22 CLINICAL CHILD PSYCHOLOGY & PSYCHIATRY 219, 222 (2017) (noting that PROMs could take time away from psychotherapy session discussions).

¹⁸⁷ *Id.*; Hoffman, *supra* note 76, at 88 (noting that the average primary care visit lasts only 15-20 minutes); Nguyen et al., *supra* note 156, at 188 (noting that a frequent complaint is "the time for patients to complete PROMs").

¹⁸⁸ Hoffman, *supra* note 76, at 90-91.

¹⁸⁹ See *supra* Parts I.B and I.C.

¹⁹⁰ Nguyen et al., *supra* note 156, at 191.

¹⁹¹ See *supra* note 51 and accompanying text; Nnenaya Q. Agochukwu, *Validity of the Patient-Reported Outcome Measurement Information System (PROMIS) Sexual Interest and Satisfaction Measures in Men Following Radical Prostatectomy*, 37 J. CLIN. ONCOL. 2017, 2017 (2019).

available electronically to multiple clinicians. If appropriate security measures are not implemented, they could also be inadvertently or intentionally disclosed to third parties or compromised through hacking.¹⁹² Because of the volume and sensitivity of the collected data, PROMS may intensify contemporary worries about privacy.

PROMs are covered by the HIPAA Privacy and Security Rules,¹⁹³ whether or not they are integrated into patients' EHRs.¹⁹⁴ Both the Privacy and Security rules apply to health plans, health care clearinghouses, health care providers who transmit health information electronically for purposes of HIPAA-relevant transactions, and their business associates.¹⁹⁵ Business associates would include all entities that work with health care providers to collect, process, and store PROMs.¹⁹⁶

The Privacy Rule establishes that, in general, covered entities must obtain patients' permission before disclosing their medical data to others.¹⁹⁷ The HIPAA Security Rule requires administrative, physical, and technical safeguards to protect the confidentiality and integrity of electronic health information.¹⁹⁸ Consequently, PROMs should not be disclosed to most third parties, such as employers or marketers, without patient consent and should be stored securely.

However, patients should be aware of significant exceptions to the HIPAA regulations. First, covered entities are permitted to divulge patients' medical information without consent for purposes of treatment, payment, and health care operations.¹⁹⁹ Thus, physicians can consult colleagues about patients, and facilities can send treatment information to insurers or use data for quality improvement activities without patients' knowledge. In addition, the Privacy Rule lists a variety of other requests to which covered entities can respond without patient authorization, such as those made for purposes of public health activities, judicial

¹⁹² Sharona Hoffman & Andy Podgurski, *In Sickness, Health and Cyberspace: Protecting the Security of Electronic Private Health Information*, 48 B.C. L. REV. 331, 332-35 (2007).

¹⁹³ 45 C.F.R. §§ 160.101-534 (2022); 45 C.F.R. §§ 164.302-.318 (2022).

¹⁹⁴ See *supra* notes 67-70 and accompanying text.

¹⁹⁵ 45 C.F.R. §§ 160.102-160.103 (2022); 42 U.S.C. §17934(a).

¹⁹⁶ 42 U.S.C. §17934(a) (2022); 45 C.F.R. 160.103 (2022). Note that the privacy of PROMs collected for non-clinical purposes (e.g. research) is also protected. The Privacy Act of 1974 prohibits federal agencies from disclosing individuals' data without their consent, unless particular exceptions apply. 5 U.S.C. § 552a(b). This safeguard would protect PROMs that are handled by the FDA and by federal programs such as Medicare or Medicaid. In addition, the federal research regulations, also known as the Common Rule, require that study participants provide informed consent for the use of any identifiable private information, which would include PROMs. 45 C.F.R. §46.116 (2022).

¹⁹⁷ 45 C.F.R. §§ 164.508 - .510 (2022).

¹⁹⁸ 45 C.F.R. §§ 164.302 -.318 (2022).

¹⁹⁹ 45 C.F.R. §164.506 (2022); U.S. Department of Health & Human Services, *Uses and Disclosures for Treatment, Payment, and Health Care Operations*, HHS.GOV, <https://www.hhs.gov/hipaa-for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html> (last reviewed Jul. 26, 2013).

and administrative proceedings, or law enforcement.²⁰⁰ There is no limit to the number of individuals who can view medical data for these permitted purposes.²⁰¹ By some estimates, between 150 and 400 individuals view each patient's EHR.²⁰²

At the same time, the HIPAA Privacy Rule's "minimum necessary" standard attempts to limit the extent of lawful disclosures. It provides that entities that disclose protected health information pursuant to a legitimate request "must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose."²⁰³ There are certain exceptions to the minimum necessary requirement, such as disclosures to clinicians for treatment purposes and disclosures required by law.²⁰⁴

De-identified data constitute another major carve-out and are entirely exempt from HIPAA coverage.²⁰⁵ Therefore, they can be disclosed without patient authorization and stored in ways that do not comply with HIPAA Security Rule standards. It is thus possible that healthcare providers will disclose de-identified PROMs to third parties for research, marketing, or other purposes.

In theory, de-identification in compliance with HIPAA instructions thoroughly protects health information. However, there can never be a one-hundred percent guarantee that data will not be re-identified.²⁰⁶ In some cases, skilled attackers may be able to re-identify data by matching them to publicly available information, such as voter registration records or news stories about individuals with illnesses or injuries.²⁰⁷

²⁰⁰ 45 C.F.R. § 164.512 (2022).

²⁰¹ *Id.*, 45 C.F.R. § 164.506 (2022).

²⁰² Merida L. Johns, *Privacy and Security of Health Information*, in JEROME H. CARTER, ELECTRONIC HEALTH RECORDS: A GUIDE FOR CLINICIANS AND ADMINISTRATORS 298 (2008).

²⁰³ 45 C.F.R. § 164.502(b) (2022).

²⁰⁴ 45 C.F.R. § 164.502(b)(2) (2022).

²⁰⁵ 45 C.F.R. § 160.103 (2022) (defining protected health information as "individually identifiable health information" that is electronically or otherwise transmitted or maintained). The HIPAA Privacy Rule provides detailed guidance regarding de-identification. It states that health information is de-identified if (1) a qualified expert determines that there is only a "very small" risk that the data can be re-identified, and (2) the expert documents the analysis used to make this determination. 45 C.F.R. § 164.514(b)(1) (2022). As an alternative de-identification method, the HIPAA Privacy Rule lists eighteen items that should be removed to render data anonymized. These include names, geographic information, phone numbers, email addresses, social security and medical record numbers, and more. 45 C.F.R. § 164.514(b)(2)(i) (2022).

²⁰⁶ Victor Janmey & Peter L. Elkin, *Re-Identification Risk in HIPAA De-Identified Datasets: The MVA Attack*, 2018 AMIA ANNU. SYMP. PROC. 1329, 1329 (2018).

²⁰⁷ NAT'L COMM. ON VITAL & HEALTH STATISTICS, REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES ON ENHANCED PROTECTIONS FOR USES OF HEALTH DATA: A STEWARDSHIP FRAMEWORK FOR "SECONDARY USES" OF ELECTRONICALLY COLLECTED AND TRANSMITTED HEALTH DATA 36 n.16 (2007), available at www.ncvhs.hhs.gov/071221lt.pdf; Sharon Hoffman & Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. REV 85, 105-07 (2012).

Sadly, there is also no guarantee that HIPAA-covered data will not be compromised by hacking or other unlawful disclosures due to security lapses. According to one source, “[i]n 2021, an average of 1.95 healthcare data breaches of 500 or more records were reported each day.”²⁰⁸ But data breach risks are not unique to PROMs and are the cost of having so many data-rich medical resources.

B. Medical Malpractice

For health care providers, a primary concern is medical malpractice. Both clinicians and health care entities can be held liable for malpractice. PROMs could potentially constitute a liability minefield for the medical community. Claims might arise because clinicians ignore PROMs that could influence important medical decisions, rely on them excessively, or fail to adopt them. This Section considers the malpractice implications of PROMs use.

1. Clinician Liability

Providers that ask patients to complete PROMs but do not review and react appropriately to them, could potentially be vulnerable to liability if patients experience adverse events after reporting that their symptoms are not improving or are worsening.²⁰⁹ For example, clinicians could potentially be sued if patients report suicidal ideation in PROM surveys and then, in the absence of intervention, commit suicide.²¹⁰

At the same time, liability could arise from inappropriate reliance on PROMs. To illustrate, psychiatrists may improperly fail to provide aggressive treatment for clinical depression if patients report in PROMs that they are less depressed. Similarly, surgeons may decide against needed surgery because patients do not report a high enough level of discomfort in PROMs.²¹¹ In both cases, PROMs should be used as a tool, but fact finders may determine that clinicians should have also conducted other testing or had face-to-face conversations with patients.²¹² Recall that patients sometimes experience survey fatigue and fail to answer questions carefully and thoughtfully.²¹³

A third possibility is that plaintiffs will bring claims against clinicians who failed to adopt PROMs that would have been helpful to their treatment. For

²⁰⁸ *Healthcare Data Breach Statistics*, HIPAA J., <https://www.hipaajournal.com/healthcare-data-breach-statistics/#:~:text=Healthcare%20Data%20Breaches%20by%20Year&text=In%202018%2C%20healthcare%20data%20breaches.records%20were%20reported%20each%20day>. (last visited Dec. 11, 2022).

²⁰⁹ Rivera et al., *supra* note 8, at 1922 (“If concerning data are not managed appropriately, those data could lead to suboptimal ... care”).

²¹⁰ See NATIONAL QUALITY FORUM, *supra* note 7, at 23.

²¹¹ See Safran & Higgins, *supra* note 63 (noting that PROMs can inform clinical decisions).

²¹² See Black, *supra* note 160, at 4 (“While some patients will not benefit from surgery, unfortunately they cannot necessarily be identified preoperatively using PROMs”).

²¹³ See *supra* notes 174-177 (discussing survey fatigue).

example, PROMs concerning pain or mental health could be critical to medical decision making because these conditions are difficult to assess without patients' subjective input.²¹⁴ Patients who feel they were injured because their doctor failed to solicit their thorough input might sue for negligence.

Medical malpractice plaintiffs suing health care professionals must establish the four elements of a negligence case.²¹⁵ These are:

- 1) The defendant owes a duty of care to the plaintiff;
- 2) The defendant breached that duty through conduct that fails to meet the applicable standard of care;
- 3) The plaintiff suffered harm or injury; and
- 4) There is a causal link between the injury and the breach of duty.²¹⁶

Courts will need to grapple with the novel and complicated question of what the standard of care with respect to PROM use will be. The standard of care in each case is determined through an assessment of whether the defendant exercised "that reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of their profession under similar circumstances."²¹⁷ This assessment generally requires expert testimony.²¹⁸ Fact-finders, therefore, should not judge clinicians based on whether they provided *optimal* care, but rather, on whether they provided *reasonably competent* care in light of the particulars of the specific case.²¹⁹ The standard of care is to be "objectively determined by reference to the availability of medical and practical knowledge which would be brought to bear in the treatment of like or similar patients under like or similar circumstances by ... physicians in the same field, given the facilities, resources and options available."²²⁰

²¹⁴ See *supra* notes 38-42, 75 and accompanying text.

²¹⁵ Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L. J. 1523, 1533-34 (2009).

²¹⁶ *Id.* at 1534; McDowell v. Brown, 392 F.3d 1283, 1295 (11th Cir. 2004); Hanson v. Grode, 90 Cal.Rptr.2d 396, 400 (Cal. Ct. App. 1999).

²¹⁷ Scott v. C.R. Bard, Inc., 231 Cal.App.4th 763, 786 (2014), quoting Alef v. Alta Bates Hospital, 5 Cal.App.4th 208, 215 (1992). See also, Day v. Johnson, 255 P.3d 1064, 1069 (Colo. 2011); Neuhaus v. DeCholnoky, 280 Conn. 190, 222 (Conn. 2006); LaSalle Bank, N.A. v. C/HCA Dev. Corp., 384 Ill. App. 3d 806, 817 (Ill. App. Ct. 2008); David M. Studdert & Mark A. Hall, *Fundamentals of Health Law: Medical Malpractice Law – Doctrine and Dynamics*, 387 N. ENGL. J. MED. 1533, 1533 (2022). A variety of statutes codify the standard of care and establish a reasonable competence standard. See e.g., ALA. CODE § 6-5-484 (2020); ARIZ. REV. STAT. § 12-563 (2020); CONN. GEN. STAT. § 52-184c (2020); FLA. STAT. ANN. § 766.102 (2020); GA. CODE ANN. § 51-1-27 (2020); NEB. REV. STAT. ANN. § 44-2810 (2020); N.H. REV. STAT. ANN. § 507-E:2 (2020).

²¹⁸ Scott, 231 Ca. App.4th at 787.

²¹⁹ See *supra* note 217.

²²⁰ Hall, 466 So.2d at 872.

Because PROMs are not yet a routine part of patient care,²²¹ there is no clear standard of care concerning their use. Whenever emerging technologies begin to be adopted, there is uncertainty about the applicable standard of care.²²²

With respect to claims that clinicians ignored information in PROMs, clinicians will likely argue that it is impossible to review and respond to all PROMs²²³ and that doing so should not be considered the standard of care. Arguably, instead of assuming that providers are scrutinizing all PROMs, patients who require attention should call the office. According to one study, family physicians have a mean of approximately 2300 patients each,²²⁴ and consequently, reviewing PROMs could be an overwhelming and unmanageable task, unless it is largely automated, as suggested later in this Article.²²⁵

In contrast, patients will argue that there is no point in taking the time to complete PROMs if clinicians simply ignore them. Arguably, requests for PROMs imply that clinicians will read and respond to them.

While there is currently no precedent involving PROMs, a few cases concerning physicians' communication with patients suggest that an argument for PROM-related liability may be viable. In *Gaffney v. Giles*, a Louisiana court of appeals upheld a lower court's determination that a physician's failure to return a patient's phone calls constituted a breach of the standard of care.²²⁶ The patient was awarded damages because his condition deteriorated as he tried and failed to reach his doctor.²²⁷ In an older case, *St. Charles v. Kender*, the court held that an HMO patient who suffered a miscarriage could assert a breach of contract claim against a doctor who ignored her phone calls.²²⁸ By extension, if patients are led to believe that health care providers will review their PROMs, plaintiffs might successfully bring medical malpractice claims based on clinicians' failure to respond to alarming PROM information.

²²¹ See *supra* notes 62-63 and accompanying text (discussing the limited extent to which PROMs have been adopted in the United States).

²²² W. Nicholson Price II, *Medical Malpractice and Black-Box Medicine*, in *BIG DATA, HEALTH LAW, AND BIOETHICS* 295, 300 (I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena & Urs Gasser eds. 2018) (discussing black-box medical algorithms and noting that providers "could be held liable for harmful use of black-box medical algorithms depending on the prevailing customary practice and the extent that custom is considered dispositive"); Amy Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine*, 23 J. LEG. MED. 449, 469 (2002) ("The variations in acceptance and assimilation of new technology raise important questions about how technology will impact a provider's legal liability where some practitioners utilize it and others do not.").

²²³ See *supra* notes 180-182 and accompanying text (discussing physician burnout).

²²⁴ Mingliang Dai, Richard C. Ingham & Lars E. Peterson, *Scope of Practice and Patient Panel Size of Family Physicians Who Work with Nurse Practitioners or Physician Assistants*, 51 FAM. MED. 311, 314 (2019).

²²⁵ See *infra* Part V.A.2.b.

²²⁶ 165 So.3d 1100, 1103 (La. App. Ct. 2015).

²²⁷ *Id.*

²²⁸ 646 N.E.2d 411, 413 (Mass. App. Ct. 1995).

Claims that clinicians did the opposite and relied excessively on PROMs in making diagnostic or treatment decisions and neglected to investigate other indicators would be treated like all claims relating to erroneous medical decision making. Courts would need to assess the degree to which reliance on the tool of PROMs to the exclusion of other tools complies with the standard of care.²²⁹

Interesting questions could also arise with respect to patients who fail to fill out PROM surveys or do not answer all questions after being informed that clinicians rely on PROMs for decision making purposes. Would sending reminders to patients or incentivizing survey completion become part of the standard of care? Would courts apply the doctrine of contributory negligence or comparative fault to patients who do not complete PROMs after being told of their importance?²³⁰

Claims that plaintiffs were injured because physicians failed to implement PROMs and thereby gather vital information would be assessed in the same manner as claims regarding other new medical technologies. For example, in *Washington v. Washington Hospital Center*, the court ruled that reasonable jurors could find that the standard of care in 1987 required hospitals to use end-tidal carbon dioxide monitors for anesthetized patients during surgery.²³¹ It thus upheld a jury verdict for a patient who suffered permanent brain injuries because of oxygen deprivation.²³²

It is possible that malpractice concerns will accelerate widespread adoption of PROMs.²³³ If courts come to expect that health care providers collect PROMs and integrate them into clinical decision making, providers will be more likely to adopt PROMs quickly to avoid deviating from the standard of care.

Ultimately, the courts will have to determine what the standard of care is in the context of PROMs.²³⁴ If litigation is brought by plaintiffs who feel they were

²²⁹ See George Maliha, Sara Gerke, I. Glenn Cohen & Ravi B. Parikh, *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*, 99 MILBANK Q. 629, 632 (2021) (discussing the use of artificial intelligence and machine learning and noting that a “physician who in good faith relies on an AI/ML system to provide recommendations may *still* face liability if the actions the physician takes fall below the standard of care and other elements of medical malpractice are met”).

²³⁰ BRIETTA R. CLARK, ERIN C. FUSE BROWN, ROBERT GATTER, ELIZABETH Y. MCCUSKEY, AND ELIZABETH PENDO, *LAW AND HEALTH CARE QUALITY, PATIENT SAFETY, AND LIABILITY* 223 (2022) (discussing contributory and comparative fault).

²³¹ 579 A.2d 177, 181 (DC Ct. App. 1990).

²³² *Id.* at 177.

²³³ Ryan Abbott, *The Reasonable computer: Disrupting the Paradigm of Tort Liability*, 86 GEO. WASH. L. REV. 1, 12 (2018) (“In its quest to reduce accidents, tort law can either accelerate the introduction of new technologies, as was the case with the use of glaucoma testing and pulse oximeters, or it can discourage the use of new technologies, as is usually the case where the standard of care is based on custom.”).

²³⁴ See Sokol & Molzen, *supra* note 222, at 469 (“The reality that the health care industry has not uniformly embraced information technology will cause courts to reexamine the standard of care and how to shape it.”)

injured and the harm is linked to PROMs, caselaw will help establish the legal standards for managing this data tool.

2. *Liability of Health Care Entities*

Aggrieved plaintiffs may wish to assert medical malpractice claims not only against clinicians, but also against health care entities. First, plaintiffs can sue health care organizations such as hospitals and clinics for the negligence of their employees, and, under agency principles, employers can be held vicariously liable for their employees' acts.²³⁵ Thus, if courts determine that clinicians can be liable for failing to react appropriately to information captured in PROMs, failing to adopt PROMs, or over-relying on PROMs, patients could use vicarious liability theories to sue health care entities. When clinicians are employees of the entity, plaintiffs can allege actual agency,²³⁶ and if clinicians are independent contractors, claimants may attempt to prove apparent agency.²³⁷

Alternatively, plaintiffs may wish to sue health care facilities directly if they believe entities have mishandled PROMs, have faulty PROM policies, or do not enforce policies appropriately. The corporate negligence doctrine, which is recognized by most states,²³⁸ establishes that health care entities are liable for failing to provide treatment that meets the standard of care.²³⁹ Hospitals (and other medical entities) have the following four duties:

- (1) a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment;
- (2) a duty to select and retain only competent physicians;
- (3) a duty to oversee all persons who practice medicine within its walls as to patient care; and
- (4) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients.²⁴⁰

To establish a prima facie case of corporate negligence, plaintiffs must show (1) that the hospital deviated from the standard of care; (2) that the hospital has actual or constructive knowledge of the flaws or procedures that caused the injury;

²³⁵ BRIETTA R. CLARK, ERIN C. FUSE BROWN, ROBERT GATTER, ELIZABETH Y. MCCUSKEY & ELIZABETH PENDO, *LAW AND HEALTH CARE QUALITY, PATIENT SAFETY, AND LIABILITY* 231-32 (9th ed. 2022).

²³⁶ *Scott v. SSM Healthcare St. Louis*, 70 S.W. 3d 560, 566-67 (2002).

²³⁷ *See Burless v. West Virginia University Hospitals, Inc.*, 601 S.E.2d 85, 92-96 (2004). In order to prevail on a theory of apparent agency, a plaintiff must establish two elements:

- (1) the hospital either committed an act that would cause a reasonable person to believe that the physician in question was an agent of the hospital, or, by failing to take an action, created a circumstance that would allow a reasonable person to hold such a belief, and
- (2) the plaintiff relied on the apparent agency relationship.

Burless, 601 S.E.2d at 95-96.

²³⁸ Erika L. Amarante, *Corporate Liability for Hospitals*, FOR THE DEFENSE (Feb. 2016), 10-11, https://www.wiggin.com/wp-content/uploads/2019/09/34467_ftd-1602-amarante.pdf.

²³⁹ *Thompson v. Nason Hosp.*, 591 A.2d 703, 707 (Pa. 1991).

²⁴⁰ *Id.*

and (3) that a causal link exists between the conduct in question and the harm.²⁴¹ Plaintiffs could sue health care organizations for mishandling or neglecting PROMs if they feel that fault lies with the entity itself.

Claims relating to failure to review and respond to PROMs or excessive reliance on PROMs could arguably fall under the duty to oversee personnel properly or to have suitable rules and policies.²⁴² Failure to implement a PROMs program in the first place (if doing so has become the standard of care) could potentially be considered a breach of the latter duty as well as the duty to maintain adequate equipment.²⁴³

III.

PROM USE IN RESEARCH AND FDA OVERSIGHT

PROMs can serve many purposes outside the clinical setting. They are frequently employed in research studies to obtain quality of life data directly from patients. The FDA has also begun to accept PROMs for certain oversight functions. This section critiques PROM use in research and FDA oversight.

A. Incorporating PROMs into Research

Many researchers are enthusiastic about incorporating PROMs into research.²⁴⁴ They note that patients have much to contribute in assessing their own symptoms and adverse events and that PROMs are an important adjunct to clinician-reported outcomes.²⁴⁵ To that end, the National Cancer Institute developed the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).²⁴⁶ The PRO-CTCAE contains “124 items representing 78 symptomatic toxicities” and is designed to be a companion to the physician-reported CTCAE.²⁴⁷ There is also a pediatric module for self-reporting by minors who are seven to seventeen years old ((Ped-PRO-CTCAE®) and a module for caregivers of minors who cannot self-report (Ped-PRO-CTCAE®[Caregiver]), and all versions are publicly available.²⁴⁸ PROMs may be particularly useful for comparative effectiveness research in which different medical interventions are

²⁴¹ Rauch v. Mike-Mayer, 783 A.2d 815, 827 (Pa. Super. Ct. 2001).

²⁴² Thompson, 591 A.2d at 707.

²⁴³ *Id.*

²⁴⁴ Kluetz et al., *supra* note 75, at 743.

²⁴⁵ *Id.*, at 743.

²⁴⁶ *Id.*; National Cancer Institute Division of Cancer Control and Population Sciences, *What is the PRO-CTCAE Measurement System?*, <https://healthcaredelivery.cancer.gov/pro-ctcae/overview.html> (last updated Jan. 28, 2022) [hereinafter NCI].

²⁴⁷ NCI, *supra* note 246; National Cancer Institute Division of Cancer Control and Population Sciences, *Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®)*, <https://healthcaredelivery.cancer.gov/pro-ctcae/> (last updated Jan. 28, 2022).

²⁴⁸ NCI, *supra* note 246.

directly compared to determine which are of greatest benefits or harm to particular patients.²⁴⁹

Nevertheless, some experts are highly critical of the way PROMs are currently used in research.²⁵⁰ According to one article, thousands of new PROM questionnaires are produced, many of which are used for only one study, and they have little impact on medical research.²⁵¹ The authors note that while PROMs are very widely employed in studies, their results are rarely reported in publications, and when they are discussed, there is often no comparison of score changes between study arms.²⁵² This article is not alone in noting that PROM data are often neglected in research publications.²⁵³

Others express additional concerns. One international consortium developed recommendations for identifying suitable statistical methods for PROM analysis, managing missing data, and other challenges.²⁵⁴ However, it noted that there is “no consensus on standards and unclear guidelines on how to analyse and interpret PRO data” collected in cancer clinical trials.²⁵⁵ It concluded that it is critical that robust findings “be derived consistently across studies to yield meaningful results” and that a great deal of work has yet to be done to finetune PROM standards for cancer studies.²⁵⁶

B. PROM Use in FDA Drug and Device Assessment and Labeling

At their best, patients’ own voices, expressed through PROMs, can play a vital role in research and regulatory oversight. PROMs are increasingly used for FDA regulatory purposes.²⁵⁷ The 21st Century Cures Act established a program under which the FDA is to evaluate the use of real world evidence to support new uses of

²⁴⁹ Hostetter & Klein, *supra* note 11; Albert W. Wu, Claire Snyder, Carolyn M. Clancy & Donald M. Steinwachs, *Adding the Patient Perspective to Comparative Effectiveness Research*, 29 HEALTH AFFAIRS 1863, 1863 (2010).

²⁵⁰ Stephen P. McKenna, Alice Heaney, Jeanette Wilburn & A. Jackson Stenner, *Measurement of Patient-Reported Outcomes. 1: The Search for the Holy Grail*, 22 J. MED. ECON. 516, 520 (2019).

²⁵¹ *Id.*

²⁵² *Id.*

²⁵³ Rivera et al., *supra* note 8, at 1911 (“A 2019 evaluation of 160 cancer trials showed nearly 50,000 participants were included in studies that failed to publish their PRO data”); Thi Xuan Mai Tran, Jungeun Park, Joonki Lee, Yuh-Seog Jung, Yoonjung Chang & Hyunsoon Cho, *Utility of the Patient-Reported Outcomes Measurement Information System (PROMIS) to Measure Primary Health Outcomes in Cancer Patients: A Systematic Review*, 29 SUPPORTIVE CARE IN CANCER 1723, 1736 (2021) (“Non-reporting of PRO results is prevalent, and this devalues the considerable contribution of participants who spend time and effort to provide their PRO information.”).

²⁵⁴ Carneel Coens et al., *International Standards for the Analysis of Quality-of-life and Patient-Reported Outcome Endpoints in Cancer Randomised Controlled Trials: Recommendations of the SISAQOL Consortium*, 21 LANCET e83, e83 (2020).

²⁵⁵ *Id.*

²⁵⁶ *Id.* at e94.

²⁵⁷ U.S. FOOD AND DRUG ADMINISTRATION, VALUE AND USE OF PATIENT-REPORTED OUTCOMES (PROs) IN ASSESSING EFFECTS OF MEDICAL DEVICES CDRH STRATEGIC PRIORITIES 2016-2017, 5 (2017), <https://www.fda.gov/media/109626/download>.

approved drugs and to help conduct post approval studies.²⁵⁸ The Act defines “real world evidence” as “data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials.”²⁵⁹ This data includes information that is generated by patients themselves.²⁶⁰

In 2022 guidance regarding medical devices, the FDA stated that use of patient-reported outcomes (PROs) is voluntary, and thus they are not currently *required* for any FDA purpose.²⁶¹ However, the FDA supports and recommends PROMs in many circumstances.²⁶²

Under the Medical Device Development Tools program, PROMs qualify for use in the development and assessment of medical devices.²⁶³ PROM-based research can be valuable for purposes of designing and developing devices that will best serve patient needs.²⁶⁴ In addition, PROMs can significantly contribute to post market surveillance, providing data about treatment success or failure after products are deployed in clinical care.²⁶⁵

If developers wish to use PROMs to meet regulatory requirements such as medical device evaluation, the FDA will determine what validity evidence is needed to render them “fit-for-purpose.”²⁶⁶ In addition, the FDA runs the Clinical

²⁵⁸ 21 U.S.C. § 355g.

²⁵⁹ 21 U.S.C. S 355g(b).

²⁶⁰ U.S. Food & Drug Administration, Real-World Evidence, <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence#:~:text=Real%2Dworld%20data%20are%20the,Claims%20and%20billing%20activities> (current as of Oct. 19, 2022).

²⁶¹ U.S. FOOD AND DRUG ADMINISTRATION, PRINCIPLES FOR SELECTING, DEVELOPING, MODIFYING, AND ADAPTING PATIENT REPORTED OUTCOME INSTRUMENTS FOR USE IN MEDICAL DEVICE EVALUATION 2 (2022), <https://www.fda.gov/media/141565/download> [hereinafter FDA 2022].

²⁶² *Id.*

²⁶³ *Id.* at 3; U.S. Food & Drug Administration, Medical Device Development Tools (MDDT), <https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt> (current as of Nov. 28, 2022).

²⁶⁴ FDA 2022, *supra* note 261, at 3-4.

²⁶⁵ *Id.* The FDA acknowledges that not all side effects of drugs and devices can be discerned “based on preapproval studies involving only several hundred to several thousand patients.” Consequently, it has post marketing surveillance and risk assessment programs designed to identify adverse events that did not manifest before a drug or device was approved. U.S. Food & Drug Administration, *Postmarket Surveillance Programs*, <https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs#:~:text=Because%20all%20possible%20side%20effects,during%20the%20drug%20approval%20process> (current as of Apr. 20, 2020).

²⁶⁶ FDA 2022, *supra* note 261, at 4-5 (“By assessing the similarities and differences between the population in the clinical study and in the development of the PRO instrument, FDA can determine whether the PRO instrument is fit-for-purpose.”). “Fit-for-Purpose” is defined as a “conclusion that the level of validation associated with a medical product development tool is sufficient to support its context of use.” *Id.* at 12.

Outcome Assessment (COA) Qualification Program.²⁶⁷ The FDA explains that “COA qualification represents a conclusion that within the stated context of use, results of assessment can be relied upon to measure a specific concept and have a specific interpretation and application in drug development and regulatory decision-making.”²⁶⁸

There is no consensus as to which PROMs should be used for FDA approval.²⁶⁹ The FDA offers several key principles that should guide incorporation of PROMs into device evaluation. They are:

1. Establish and define the concept of interest (COI) the PRO instrument is intended to capture;
2. Clearly identify the role of the PRO (e.g., primary, secondary, ancillary, effectiveness, safety) in the clinical study protocol and statistical analysis plan;
3. Provide evidence showing that the PRO instrument reliably assesses the COI; and
4. Effectively and appropriately communicate the PRO-related results in the [product] labeling to inform healthcare provider and patient decision making.²⁷⁰

Drug and device “labeling” includes not only labels pasted on containers, but also other written, printed, or graphic material on items, their containers, wrappers, or other matter that accompany them.²⁷¹ In 2009 the FDA issued guidance that describes how the FDA reviews and assesses PROM instruments that are used to develop evidence for claims in medical product labeling.²⁷² According to one source, approximately twenty-six percent of new drugs approved from 2016 to 2020 included PRO-related statements in labeling.²⁷³

The FDA is developing further guidance regarding PROM use. These include draft guidance on “Core Patient-Reported Outcomes in Cancer Clinical Trials”²⁷⁴ and a “Patient-Focused Drug Development Guidance Series for Enhancing the

²⁶⁷ U.S. Food & Drug Administration, Clinical Outcome Assessment (COA) Qualification Program, <https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/clinical-outcome-assessment-coa-qualification-program> (current as of Nov. 9, 2021).

²⁶⁸ *Id.*

²⁶⁹ Warsame & D’Souza, *supra* note 18, at 2291.

²⁷⁰ FDA 2022, *supra* note 261, at 4.

²⁷¹ 21 U.S.C. §321(m).

²⁷² U.S. FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY PATIENT-REPORTED OUTCOME MEASURES: USE IN MEDICAL PRODUCT DEVELOPMENT TO SUPPORT LABELING CLAIMS (2009), <https://www.fda.gov/media/77832/download>.

²⁷³ Gnanasakthy et al., *supra* note 10, at 650.

²⁷⁴ U.S. FOOD AND DRUG ADMINISTRATION, CORE PATIENT-REPORTED OUTCOMES IN CANCER CLINICAL TRIALS: GUIDANCE FOR INDUSTRY, DRAFT GUIDANCE (June 2021), <https://www.fda.gov/media/149994/download>.

Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making.”²⁷⁵ Consequently, it is not inconceivable that the FDA will ultimately require PROM use for some regulatory purposes once it refines its approach to this tool.

IV.

PROM USE FOR PERFORMANCE MEASUREMENT AND INSURANCE COVERAGE

Policy makers in the U.S. have long expressed a commitment to achieving value-based care that rewards health care providers for high-quality services and outcome improvements.²⁷⁶ Such a system requires the ability to measure quality of care and health outcomes accurately, and, according to some advocates, PROMs are a critical component of these measurements.²⁷⁷ Thus, the concept of patient-reported outcome performance measures (PRO-PM) has emerged.²⁷⁸ A PRO-PM is a “performance measure that is based on patient-reported outcomes assessed through data, often collected through a PROM and then aggregated for ... [a] healthcare entity.”²⁷⁹ CMS endorses the use of PRO-PMs for performance improvement and accountability purposes.²⁸⁰

Under the CMS Quality Payment Program (QPP), created by the Medicare Access and CHIP Reauthorization Act of 2015,²⁸¹ CMS rewards clinicians for high performance levels and reduces payments for sub-standard performance.²⁸² Clinicians have two QPP options: 1) the Merit-based Incentive Payment System (MIPS) or 2) Advanced Alternative Payment Models. PROMs are a priority measurement category for MIPS.²⁸³ Furthermore, CMS is incorporating PRO-PMs

²⁷⁵ U.S. Food & Drug Administration, *Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making*, <https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical> (current as of Nov. 22, 2022).

²⁷⁶ David Lansky, *Reimagining a Quality Information system for US Health Care*, HEALTH AFFAIRS FOREFRONT, Jan. 25, 2022, <https://www.healthaffairs.org/doi/10.1377/forefront.20220120.301087/>.

²⁷⁷ *Id.*

²⁷⁸ NATIONAL QUALITY FORUM, *supra* note 7, at 3.

²⁷⁹ *Id.*

²⁸⁰ *Id.*

²⁸¹ Pub. L. No. 114-10, 129 Stat. 87 (2015) (codified as amended in scattered sections of 16, 26, and 42 U.S.C.). CHIP is the Children's Health Insurance Program. See *The Children's Health Insurance Program (CHIP)*, HEALTHCARE.GOV, <https://www.healthcare.gov/medicaid-chip/childrens-health-insurance-program/> (last visited Dec. 11, 2022).

²⁸² Department of Health and Human Services, *Quality Payment Program Overview*, <https://qpp.cms.gov/about/qpp-overview> (last visited Dec. 11, 2022).

²⁸³ Centers for Medicare & Medicaid Services, *MACRA*, CMS.GOV, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs> (last modified Apr. 1, 2022); Code Technology, *Merit-Based Incentive Payment System (MIPS)*,

into its Meaningful Measures 2.0 initiative, which aims to streamline quality measures and “promote innovation and modernization of all aspects of quality.”²⁸⁴ Additionally, CMS and the National Quality Forum have undertaken an initiative called “Building a Roadmap from Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures.”²⁸⁵ The project aims to provide guidance regarding PRO-PMs that will be used in CMS accountability programs such as alternative payment models and was scheduled for completion in late 2022.²⁸⁶ To date, however, PRO-PMs have constituted only five percent of the measures that were used by federal programs and endorsed by the National Quality Forum.²⁸⁷

Private insurers have used PROMs as well.²⁸⁸ In 2013, Blue Cross Blue Shield of Massachusetts (BCBSMA) and providers participating in its Alternative Quality Contract (AQC) program²⁸⁹ collaboratively selected conditions for initial PROM implementation.²⁹⁰ The chosen conditions were depression and knee/hip pain, which had well-recognized, validated PROMs.²⁹¹ BCBSMA paid providers to participate in the PROM program, and, during 2013-2015 participation was voluntary.²⁹² In 2016, BCBSMA transitioned to requiring participation from AQC providers, expanded the number of conditions for PROM adoption, and continued to pay providers for participation.²⁹³ It did not make any payment adjustments based on performance as reflected in PROM scores so that clinicians would not be

<https://www.codetechnology.com/mips/> (last visited Dec. 11, 2022); NATIONAL QUALITY FORUM, *supra* note 7, at 23.

²⁸⁴ Centers for Medicare & Medicaid Services, *Meaningful Measures 2.0: Moving from Measure Reduction to Modernization*, CMS.GOV, <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization> (last modified June 17, 2022).

²⁸⁵ National Quality Forum, *Building a Roadmap from Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures*, <https://www.qualityforum.org/ProjectDescription.aspx?projectID=93898> (last visited Dec. 11, 2022).

²⁸⁶ *Id.*

²⁸⁷ Amir Qaseem, Samantha Tierney, Eileen D. Barrett, Catherine H. MacLean, Andrew Dunn, and Nick Fitterman, *Recommending Caution in Patient-Reported Outcome-Based Performance Measurement*, 174 ANN. INTERN. MED. 1161, 1161 (2021).

²⁸⁸ Neubert et al., *supra* note 14, at 1-2 (“The breadth to which insurers use patient-reported data in their business models varies greatly.”).

²⁸⁹ The Alternative Quality Contract is “an innovative global payment model that uses a budget-based methodology, which combines a fixed per-patient payment (adjusted annually for health status and inflation) with substantial performance incentive payments (tied to the latest nationally accepted measures of quality, effectiveness, and patient experience).” Primary Care Collaborative, *Blue Cross Blue Shield Massachusetts - Alternative Quality Contract Statewide*, <https://www.pcpcc.org/initiative/blue-cross-blue-shield-massachusetts-alternative-quality-contract> (last updated March 2019).

²⁹⁰ Massachusetts Medical Society, *supra* note 18, at 5; Safran & Higgins, *supra* note 63.

²⁹¹ Massachusetts Medical Society, *supra* note 18, at 5; Safran & Higgins, *supra* note 63.

²⁹² Safran & Higgins, *supra* note 63.

²⁹³ *Id.* The expanded set of conditions included “low back pain, prostate cancer, other cancers with active treatment, and coronary artery disease.”

concerned that participation could lead to financial penalties.²⁹⁴ BCBSMA plans to roll out its PROM program in three phases: 1) paying providers for PROM adoption, data sharing, and learning; 2) using collected data to inform clinical decision making; and 3) eventually, using collected data to adjust payment for performance outcomes and promote accountability.²⁹⁵ Some insurers may also use PROMs to determine which physicians should be included in their networks.²⁹⁶

As noted earlier, advocates argue that validated PROMs that are implemented correctly can have a positive impact on clinical decision making and cost savings, which would also benefit health care payers.²⁹⁷ For example, BCBSMA found that patients whose PROMs indicated that they were high functioning at baseline (approximately eight percent of its cohort) did not benefit from hip and knee replacement surgery and could feel worse because of the procedure.²⁹⁸ Thus, PROM assessment could spare some patients from undergoing a painful and expensive surgery and recovery period at the same time that it spares insurers from paying for unnecessary procedures.²⁹⁹

Other commentators caution against use of PROMs for insurance purposes at this time.³⁰⁰ The American College of Physicians (ACP) asserts that more data are needed to establish that PRO-PMs in truth enhance quality of care and can be used to compare clinician performance accurately.³⁰¹ The ACP notes that outcomes can be affected by factors that are out of the physicians' control, such as patient compliance with treatment protocols or access to family and other support systems.³⁰² Moreover, some physicians could wrongly be penalized because they treat very sick patients or members of vulnerable communities whose outcomes are likely to be suboptimal even if they receive excellent care.³⁰³ Skilled analysts would need to adjust for such factors.

The Massachusetts Medical Society warns against unintended consequences of using PROMs for performance measurement purposes.³⁰⁴ If reimbursement were to depend on PROM scores, some medical decisions might be driven by health care providers' desire to maximize their earnings, and such decisions may not always be

²⁹⁴ *Id.*

²⁹⁵ Massachusetts Medical Society, *supra* note 18, at 6.

²⁹⁶ Neubert et al., *supra* note 14, at 7.

²⁹⁷ *Id.*, at 5 (noting that preliminary European studies show that "PROMs do support more evidence-based decision-making and value-based care delivery"); *see supra* Part I.B.

²⁹⁸ Safran & Higgins, *supra* note 63.

²⁹⁹ *Id.*

³⁰⁰ Qaseem et al., *supra* note 287, at 1161.

³⁰¹ *Id.* at 1161. *See also* Holmes et al., *supra* note 38 at 254 ("There is no definitive evidence as to whether PROMs have an impact on health status, with only some studies showing significant differences.").

³⁰² Qaseem et al., *supra* note 287, at 1161.

³⁰³ *Id.*

³⁰⁴ Massachusetts Medical Society, *supra* note 18, at 9.

in patients' best interest.³⁰⁵ Thus, clinicians may opt for the least uncomfortable diagnostic tests so that patients do not report increased anxiety or pain, even if more uncomfortable tests may have been better diagnostic tools. This is not merely a hypothetical concern. A United Kingdom initiative that linked financial rewards to swift access to care may have eroded continuity of care, which is important for many patients with complex needs.³⁰⁶ Health care organizations were incentivized to furnish access to any provider as quickly as possible, so patients were given appointments with clinicians who knew nothing about them.³⁰⁷

PROMs require extensive validation, and their use requires sound risk adjustment strategies.³⁰⁸ PROM programs that are poorly implemented by insurers could penalize clinicians that are providing the best care possible under the circumstances. They could also deprive patients of needed treatments because of erroneous PROM-based assumptions about their functionality or discomfort.³⁰⁹ Both the ACP and the Massachusetts Medical Society caution that it is premature to rely on PROMs for insurance purposes.³¹⁰

V.

RECOMMENDATIONS

In an ideal world, physicians or other skilled clinicians would have ample time to speak with patients about their symptoms, complaints, and medical progress. But medicine is all too often a profit-driven industry, pressuring providers to limit the duration of patient encounters and pack their schedules.³¹¹ In light of these realities, PROMs can potentially fill important data gaps.³¹² But much work remains to be done to address considerable PROM deficiencies and concerns that can lead to liability. Whether these shortcomings can be consistently overcome is still in question. This part formulates recommendations for technical and administrative improvements as well as legal and policy interventions.

³⁰⁵ *Id.*

³⁰⁶ *Id.*

³⁰⁷ *Id.*

³⁰⁸ Qaseem et al., *supra* note 287, at 1161-62. *See also supra* notes 118-128 and accompanying text (discussing validation). Risk adjustment can be defined as “A statistical process that takes into account the underlying health status and health spending of the enrollees in an insurance plan when looking at their health care outcomes or health care costs.” HealthCare.gov, *Risk Adjustment*, <https://www.healthcare.gov/glossary/risk-adjustment/> (last visited Dec. 11, 2022).

³⁰⁹ *See* Black et al., *supra* note 160, at 3 (cautioning against using PROMs to crudely ration care and relating that UK PROM data was “misinterpreted as showing that 20,000 hernia and varicose vein operations and 16,000 hip and knee replacements each year should not take place”).

³¹⁰ Massachusetts Medical Society, *supra* note 18, at 10 (“since PROMs implementation remains in its infancy ... PROMs results should not be used to compare providers or outcomes for payment”); Qaseem et al., *supra* note 287, at 1162 (advising caution “until PRO-PMs are developed in a rigorous manner and physicians can seamlessly integrate patient-reported data collection into practice”).

³¹¹ Hoffman, *supra* note 76, at 87-92.

³¹² *See supra* Part I.B (discussing PROM benefits).

A. Technical and Administrative Recommendations

Many experts have offered recommendations to assist health care providers and researchers in establishing PROM programs.³¹³ Thoughtful selection and implementation of PROMs by qualified experts should provide a degree of protection against liability risks and render PROMs better fit for research, use by the FDA and CMS, and other purposes.

1. PROM Selection

Selecting appropriate PROMs for inclusion in surveys can be very challenging and is vital to the effectiveness of any PROM initiative. Hundreds of potentially relevant PROMs are often available, and their quality may be difficult to discern.³¹⁴ Those tasked with PROM selection (called “implementers” below) must carefully contemplate what they hope to achieve, including what specific information they wish to gather and how it will be used.³¹⁵ PROM selection requires a literature review and thorough research.³¹⁶ Below are several key components of a successful selection process.

a. Obtain Stakeholder Input

PROMs selection requires input from diverse stakeholders.³¹⁷ These can include computer system administrators, technical experts, clinicians, patients, family members, caregivers, and others.³¹⁸ It may be prudent to establish a formal selection committee to ensure that such input is obtained.³¹⁹ It is particularly important to engage with patients to determine whether they will view PROMs favorably.³²⁰ Patients should be asked whether they find proposed PROMs to be accessible, understandable, or offensive in any way.³²¹

b. Select PROMs that Align with Goals

Implementers should identify the “focus, scope, and type” of PROMs that will support both treatment of individual patients and institutional goals.³²² For example, a key decision is whether to use generic PROMs, condition-specific PROMs, or a combination of both.³²³ PROM selection should be informed by a

³¹³ See e.g. Al Sayah et al., *supra* note 19, at 3-4; Massachusetts Medical Society, *supra* note 18; NATIONAL QUALITY FORUM, *supra* note 7, at 5-23; Rivera et al., *supra* note 8.

³¹⁴ Churruca et al., *supra* note 127, at 1021.

³¹⁵ Churruca et al., *supra* note 127, at 1021

³¹⁶ NATIONAL QUALITY FORUM, *supra* note 7, at 7.

³¹⁷ Sivan et al., *supra* note 29, at 1.

³¹⁸ Al Sayah et al., *supra* note 19, at 3; NATIONAL QUALITY FORUM, *supra* note 7, at 9.

³¹⁹ Al Sayah et al., *supra* note 19, at 3.

³²⁰ *Id.* at 102; CMS 2022, *supra* note 6, at 7; Rivera et al., *supra* note 8, at 1915 (discussing the need for patient input regarding PROMs that will be used in research).

³²¹ Al Sayah et al., *supra* note 19, at 4.

³²² *Id.* at 3.

³²³ Churruca et al., *supra* note 127, at 1021.

clear understanding of what outcomes clinicians or researchers wish to measure.³²⁴ Institutional goals might include performance evaluation, health care delivery improvements, and treatment cost analyses.

c. Select PROMs that Meet Practical Needs

Practical considerations are no less important than other factors.³²⁵ PROM questions should be written in clear, accessible language, and for some patient populations, multiple languages will be needed.³²⁶ Some practices or research projects include many patients with cognitive decline and, to the extent possible, their PROMs should be appropriate for such patients.³²⁷

In addition, patients have limited attention spans and tolerance for answering queries, so PROM questionnaires must not be excessively lengthy.³²⁸ Computer adaptive technology can be helpful in limiting patient burden because it tailors questionnaires to particular patients based on their responses.³²⁹ For example, to avoid survey fatigue, PROMIS often limits the number of queries to four to six when computer adaptive technology is used.³³⁰ However, implementers must also ensure that thoroughness is not sacrificed for the sake of brevity.

Another practical consideration is cost. Implementers must determine whether PROMs will strain their budget and may opt for PROMs that are publicly available rather than those that require licensing fees.³³¹

d. Evaluate PROM Attributes Prior to Selection

Implementers must examine the psychometric properties of proposed PROMs.³³² Implementers should look for evidence of reliability, validity, responsiveness, interpretability, and appropriateness for particular patient

³²⁴ NATIONAL QUALITY FORUM, *supra* note 7, at 10; Rivera et al., *supra* note 8, at 1913 (discussing the importance of clear research questions, rationales for PROM assessment, objectives, and hypotheses).

³²⁵ Al Sayah et al., *supra* note 19, at 3.

³²⁶ NATIONAL QUALITY FORUM, *supra* note 7, at 10; Rivera et al., *supra* note 8, at 1914-15 (discussing barriers to PROM completion in research).

³²⁷ See Kramer & Schwartz, *supra* note 156, at 1708-12 (discussing “PRO design features to optimize cognitive Accessibility”).

³²⁸ See *supra* notes 174-177 and accompanying text (discussing survey fatigue).

³²⁹ See *supra* notes 64-66 and accompanying text.

³³⁰ PROMIS Health Organization, *What is PROMIS*, <https://www.promishealth.org/57461-2/#:~:text=PRMIS%20measures%20have%20been%20developed,precision%20than%20most%20conventional%20measures>. (last visited Dec. 11, 2022).

³³¹ Al Sayah et al., *supra* note 19, at 3; NATIONAL QUALITY FORUM, *supra* note 7, at 10.

³³² NATIONAL QUALITY FORUM, *supra* note 7, at 10. Psychometric properties “provide information about a test’s appropriateness, meaningfulness, and usefulness—in other words, its validity.” *Psychometric Properties*, PSYCHOLOGY, <http://psychology.iresearchnet.com/counseling-psychology/personality-assessment/psychometric-properties/> (last visited Dec. 11, 2022).

populations and diseases.³³³ To that end, PROMs endorsed by PROMIS are often a good choice.³³⁴ In addition, implementers should verify that selected PROMs have been used successfully by other entities in similar circumstances.³³⁵ Further guidance for PROM review is found in a variety of resources, two of which are the “COSMIN Guideline for Systematic Reviews of Patient-Reported Outcome Measures”³³⁶ and the Terwee criteria for measurement properties of health status questionnaires.³³⁷

e. Conduct a Pilot Program

Prior to full-scale launch of PROMs, implementers should conduct a pilot program to identify any pitfalls that were missed during the selection process.³³⁸ The pilot program should evaluate how easily PROMs can be integrated into clinical workflow and how well they serve their intended purposes.³³⁹

2. PROM Implementation

Implementing PROMs can be no less challenging than selecting them. The following are several essential components of the implementation process.

a. Cultivate Stakeholder Buy-In

Implementers should build enthusiasm for PROMs among all stakeholders, including providers, staff, patients, and technical experts.³⁴⁰ It is particularly important to have one or more clinician champions to promote appreciation of PROMs' benefits and acceptance of the program.³⁴¹

b. Minimize Burdens Associated with PROMs

³³³ Al Sayah et al., *supra* note 19, at 4; Ethan Basch et al., *Methods for Developing Patient-Reported Outcome-Based Performance Measures (PRO-PMs)*, 18 VALUE IN HEALTH 493, 500 (2015). See *supra* Parts I.C.1.a and I.C.1.e for a discussion of reliability, validity, responsiveness, and interpretability.

³³⁴ Evans et al., *supra* note 53, at 350 (noting that PROMIS is the gold-standard for PROMs); Massachusetts Medical Society, *supra* note 18, at 6; Wong & Meeker, *supra* note 71, at 1 (finding that PROMIS physical health computerized adaptive test domains “are reliable, responsive, and interpretable in most contexts of patient care throughout all orthopaedic surgery subspecialties”).

³³⁵ Basch et al., *supra* note 333, at 500; NATIONAL QUALITY FORUM, *supra* note 7, at 9.

³³⁶ C. A. C. Prinsen, *COSMIN Guideline for Systematic Reviews of Patient-Reported Outcome Measures*, 27 QUALITY LIFE RES. 1147, 1148-56 (2018).

³³⁷ Caroline B. Terwee et al., *Quality Criteria Were Proposed for Measurement Properties of Health Status Questionnaires*, 60 J. CLIN. EPIDEMIOLOGY 34, 34-41 (2007). See also Eric K. H. Chan, Todd C. Edwards, Kirstie Haywood, Sean P. Mikles & Louise Newton, *Implementing Patient-Reported Outcome Measures in Clinical Practice: A Companion Guide to the ISOQOL User's Guide*, 28 QUALITY OF LIFE RESEARCH 621, 624 (2019) (listing other resources).

³³⁸ Al Sayah et al., *supra* note 19, at 4; CMS 2022, *supra* note 6, at 6.

³³⁹ Al Sayah et al., *supra* note 19, at 4 (“It is important to test these tools with the population on which the measure focuses.”).

³⁴⁰ NATIONAL QUALITY FORUM, *supra* note 7, at 14.

³⁴¹ *Id.* at 14-15; Massachusetts Medical Society, *supra* note 18, at 7.

PROM completion should be minimally burdensome for patients.³⁴² To that end, implementers might provide patients with options, such as using either a tablet computer or a patient portal and completing PROMs either at the clinical visit or at home.³⁴³ Implementers should also be mindful of the frequency of PROM administration to avoid redundant and unnecessary data collection.³⁴⁴ Thus, administration frequency should be included in PROM specifications. The value of PROMs should be explained to patients, and clinicians should demonstrate their usefulness by referring to patients' PROM scores during visits.³⁴⁵

Health care organizations should also ensure that PROMs are not excessively cumbersome for clinicians.³⁴⁶ Staff members should be tasked with the work of educating patients about PROMs, asking them to complete PROMs, and sending reminders if necessary.³⁴⁷

Initial PROM review could be assigned to someone other than the physician. Trusted nurses or other clinicians could read completed PROM questionnaires and create short summaries for physicians. They would then alert doctors to any responses that require special attention.

c. Harness Artificial Intelligence

Potentially, an even better approach is to automate PROM review using artificial intelligence (AI). AI algorithms can analyze vast amounts of information and make decisions based on the data.³⁴⁸

AI could assess each patient's PROMs, provide physicians with very brief summaries, and alert clinicians to any alarming data that should not be ignored. The alert could appear prominently on the opening screen of the patient's EHR.

Furthermore, AI could discern patterns.³⁴⁹ It could highlight responses or trends in responses that indicate the failure of treatment or worsening of the patient's condition. It could also identify patterns of responses that are characteristic of particular conditions that the patient might have.

d. Adopt Strategies for PROM Interpretation, Risk Adjustment, and Missing Data

³⁴² Massachusetts Medical Society, *supra* note 18, at 7; NATIONAL QUALITY FORUM, *supra* note 7, at 16.

³⁴³ NATIONAL QUALITY FORUM, *supra* note 7, at 16.

³⁴⁴ *Id.* at 10.

³⁴⁵ *Id.* at 17; Massachusetts Medical Society, *supra* note 18, at 7.

³⁴⁶ NATIONAL QUALITY FORUM, *supra* note 7, at 17.

³⁴⁷ *Id.*

³⁴⁸ Darrell M. West & John R. Allen, *How Artificial Intelligence Is Transforming the World*, BROOKINGS (Apr. 24, 2018), <https://www.brookings.edu/research/how-artificial-intelligence-is-transforming-the-world/>.

³⁴⁹ *Id.*

In the clinical setting, physicians must be able to understand PROM scores and know how to respond to them.³⁵⁰ They must be able to determine whether score changes over time are clinically meaningful and actionable.³⁵¹ Implementers should ensure that educational materials are available to train clinicians with respect to PROM interpretation.³⁵²

If PROMs will be used for nonclinical purposes, such as performance measurement, research, or quality improvement, a proper analysis plan must be in place.³⁵³ This includes statistical adjustment for problems such as response bias and nonresponders as well as mechanisms to address missing data.³⁵⁴ For example, to compensate for missing data, analysts may collect auxiliary information that is associated with the patient-reported outcome in question (e.g. diagnostic test results) or use statistical machine learning techniques to make adjustments.³⁵⁵ The process of estimating missing data based on known data points is called imputation.³⁵⁶

e. Incorporate PROMs data into EHR Systems

To be optimally useful in clinical practice, PROMs data should be incorporated into EHR systems.³⁵⁷ Such integration helps physicians use PROMs because they can view them when checking other information in patients' records. It also facilitates PROM use in research and quality improvement initiatives that will utilize EHRs. EHRs should display PROM scores in ways that are easy to access, read, and understand.³⁵⁸

B. Legal and Policy Interventions

The legal and policy communities can employ several strategies to facilitate PROM implementation and address its legal implications. Key areas of focus are privacy, medical malpractice, and financial incentives for PROM adoption.

1. Privacy

³⁵⁰ NATIONAL QUALITY FORUM, *supra* note 7, at 20.

³⁵¹ *Id.*

³⁵² *Id.*

³⁵³ Basch et al., *supra* note 333, at 500.

³⁵⁴ *Id.*; Rivera et al., *supra* note 8, at 1916 (discussing methods to minimize missing data in research studies, such as reminders and notifications to participants). *See supra* note 308 and accompanying text for discussion of risk adjustment. *See supra* notes 131-134 for discussion of response bias and notes 142-153 and accompanying text for discussion of missing data and nonresponders.

³⁵⁵ Ayilara et al., *supra* note 143. *See also* CELLA ET AL., *supra* note 31 at 35-36 (discussing "statistical methods of adjustment).

³⁵⁶ Jonathan A. C. Sterne et al., *Multiple Imputation for Missing Data in Epidemiological and Clinical Research: Potential and Pitfalls*, 338 *BMJ* b2393 (2009), <https://www.bmj.com/content/338/bmj.b2393>.

³⁵⁷ CELLA ET AL., *supra* note 31 at 52-54; NATIONAL QUALITY FORUM, *supra* note 7, at 21-22. *See also supra* notes 67-71 (discussing integration of PROMs into EHRs).

³⁵⁸ NATIONAL QUALITY FORUM, *supra* note 7, at 22.

PROMs can include a plethora of data about sensitive and deeply private matters such as sexual function and mental health.³⁵⁹ Routine documentation of such patient-provided information raises acute privacy concerns.

In response, the HIPAA Privacy Rule's minimum necessary provision should be modified.³⁶⁰ Entities that request patient records and are entitled to receive them because of patient consent or a HIPAA exception should not automatically receive PROMs. Instead, PROMs should be disclosed to requesters only if they have asked for them specifically and explained why they need them. Covered entities should be empowered to assess justifications for PROM requests in order to approve or deny them just as they already are tasked with determining what constitutes the minimum necessary response for all requests.³⁶¹ These assessments should be carefully conducted by experts such as privacy officers so that disclosures are not simply rubberstamped. PROMs should be stored in EHRs in ways that make them easy to identify and withhold when other data are disclosed.

The proliferation of sensitive data provided through PROMs could further intensify data security concerns. To promote compliance with the HIPAA Security Rule, The U.S. Department of Health and Human Services offers numerous data security resources on its website.³⁶² It should continue to update these resources as technology changes and experts develop new recommendations.

Health care providers must also be vigilant about data security and ensure that skilled professionals are tasked with its maintenance. Some commentators have decried health care providers' lack of preparedness for cybersecurity attacks.³⁶³ According to one report, seventy-nine percent of data breaches in 2020 involved

³⁵⁹ See e.g. Rasa Ruseckaite et al., *Evaluation of the Acceptability of Patient-Reported Outcome Measures in Women Following Pelvic Floor Procedures*, 31 QUALITY LIFE RES. 2213, 2214 & 2217 (2022).

³⁶⁰ 45 C.F.R. § 164.502(b) (2022); see *supra* notes 203-204 and accompanying text.

³⁶¹ U.S. Department of Health & Human Services, *Minimum Necessary Requirement*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/minimum-necessary-requirement/index.html> (last reviewed Jul. 26, 2013) (“For non-routine disclosures and requests, covered entities must develop reasonable criteria for determining and limiting the disclosure or request to only the minimum amount of protected health information necessary to accomplish the purpose of a non-routine disclosure or request.”).

³⁶² U.S. Department of Health and Human Services, *Security Rule Guidance Material*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html> (last reviewed Nov. 1, 2022).

³⁶³ Devin Partida, *5 Biggest Challenges of Health Care Data Security in 2022*, HEALTH IT ANSWERS, Feb. 23, 2022, <https://www.healthitanswers.net/5-biggest-challenges-of-health-care-data-security-in-2022/> (“Medical organizations’ vast amounts of sensitive patient data make them prime targets, and many lack the expertise and tools necessary to protect themselves”); Emily Skahill & Darrell M. West, *Why Hospitals and Healthcare Organizations Need to Take Cybersecurity More Seriously*, BROOKINGS, Aug. 9, 2021, <https://www.brookings.edu/blog/techtank/2021/08/09/why-hospitals-and-healthcare-organizations-need-to-take-cybersecurity-more-seriously/>.

healthcare organizations.³⁶⁴ As others have noted, “Just as hand washing is a foundational element of modern medicine, cyber hygiene must be regarded as a basic and essential component of a functioning medical system.”³⁶⁵

2. Medical Malpractice Liability

Clinicians and health care entities should be aware of the potential for malpractice liability associated with PROMs.³⁶⁶ Liability could arise from failure to review and address data provided in PROMs, excessive reliance on PROMs, or failure to adopt PROMs that have become the standard of care.³⁶⁷ Medical malpractice attorneys should learn to investigate PROM use when representing both plaintiffs and defendants. For its part, the medical community should undertake efforts to minimize the risk of PROM-related litigation, including formulating clinical practice guidelines for health care providers about PROM implementation and educating patients about PROM use.

a. The Role of PROMs in Litigation

In preparing for litigation, both plaintiffs’ attorneys and defense attorneys should investigate whether PROMs were used in the course of treatment. Plaintiffs’ attorneys should ask clients whether they completed PROMs, what information they provided, whether physicians discussed PROMs with them, and whether they believe their doctors ignored PROM data. Defense attorneys should likewise ask clients whether they used PROMs and how they handled data provided through PROMs. Discovery should routinely include queries about PROMs, such as whether they were utilized, reviewed, or served as the basis for any decision.

b. Clinical Practice Guidelines

Health care providers should proceed with caution when implementing PROM programs and selecting PROMs. Ideally, trustworthy professional organizations and government entities will develop clinical practice guidelines (CPG) that providers can follow in implementing PROM programs.³⁶⁸ CPGs are “statements that include recommendations intended to optimize patient care.”³⁶⁹ Providers would benefit from guidance regarding the incorporation of PROMs into clinical practice. CPGs could include the technical guidance regarding PROM selection and

³⁶⁴ Jessica Davis, *Healthcare Accounts for 79% of All Reported Breaches, Attacks Rise 45%*, HEALTH IT SECURITY, Jan. 5, 2021, <https://healthitsecurity.com/news/healthcare-accounts-for-79-of-all-reported-breaches-attacks-rise-45>.

³⁶⁵ Skahill & West, *supra* note 363.

³⁶⁶ *See supra* Part II.B.

³⁶⁷ *Id.*; Michelle M. Mello, *of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 648-49 (2001).

³⁶⁸ *See* Hoffman & Podgurski, *supra* note 215, at 1570-72 (discussing clinical practice guidelines).

³⁶⁹ American Academy of Family Physicians, *Clinical Practice Guideline Manual*, <https://www.aafp.org/family-physician/patient-care/clinical-recommendations/cpg-manual.html> (last visited Dec. 11, 2022).

administration provided above. They could also address how to induce as many patients as possible to complete PROMs, how to review PROMs efficiently, how to determine whether PROM scores require any response, the extent to which PROMs should be discussed during office visits, and more.

It is unclear whether following CPGs could support a defense in a medical malpractice lawsuit.³⁷⁰ Some experts argue that CPGs should never be admissible in court as evidence of the standard of care because they constitute recommendations rather than proof of actual customary medical practice.³⁷¹ Nevertheless, several courts have permitted litigants to use CPGs as evidence regarding the standard of care.³⁷²

Regardless of CPGs' admissibility, carefully formulated and widely disseminated guidance would be valuable for health care providers as they transition to implementing PROMs. It could prevent them from making obvious mistakes that could lead to malpractice litigation and help them operate in ways that promote patients' trust and cooperation.

c. Patient Education and Notice

Providers would be wise to communicate clearly with patients regarding how PROMs will be used and what expectations patients should have with respect to them.³⁷³ Patients who are asked to complete PROMs should be given verbal and written explanations of whether doctors will review PROMs in a timely fashion and contact patients about them when appropriate. If PROMs will not be routinely reviewed, patients should be told why they are being asked to complete PROMs (e.g. for quality improvement purposes) and instructed that they should not assume their physicians are aware of all the data they have provided in PROM surveys.

On the other hand, if doctors plan to rely on PROMs in making medical decisions because they do not have adequate time for lengthy discussions during patient encounters, it is particularly important that patients be clearly informed that it is vital that they complete their PROM surveys. Patients must be warned that their care might be compromised if they ignore requests for PROMs or answer surveys only partially, thereby withholding important information from clinicians.

³⁷⁰ Maxwell J. Mehlman, *Professional Power and the Standard of Care in Medicine*, 44 ARIZ. ST. L.J. 1165, 1230-32 (2012) (discussing the role of medical practice guidelines as evidence of the standard of care).

³⁷¹ Joseph P. McMenamin, Wendy Teo & B. Sonny Bal, *Medicolegal Sidebar: Clinical Practice Guidelines—Do They Reduce Professional Liability Risk?*, 478 CLIN. ORTHOP. RELAT. RES. 23, 23 (2020); Mello, *supra* note 367, at 648.

³⁷² Hoffman & Podgurski, *supra* note 215, at 1570-72; McMenamin et al., *supra* note 371, at 23-24; Mello, *supra* note 367, at 663-67 (discussing the role of CPGs in litigation).

³⁷³ See *supra* Part II.B.1 and accompanying text (discussing liability concerns relating to physicians' management of PROMs).

Such notice would be consistent with other notice practices in the medical arena. The HIPAA Privacy Rule requires health care providers to give patients notice of their privacy practices.³⁷⁴ The American Medical Association's Code of Medical Ethics Opinion 2.3.1 addresses electronic communication with patients.³⁷⁵ It advises physicians to "[n]otify the patient of the inherent limitations of electronic communication, including possible breach of privacy or confidentiality ... and possible delays in response."³⁷⁶ A similar notice regarding PROMs would help patients understand their function and limitations and potentially prevent litigation. Written notices should preferably be accompanied by verbal explanations and perhaps training videos to reinforce patient understanding and learning.³⁷⁷ Documentation showing that patients received this guidance could also serve as compelling evidence in clinicians' defense.

3. PROM Use by Regulatory Agencies

The FDA and CMS do not presently require PROMs for any oversight purpose, though regulated entities have the option of submitting them to meet certain requirements.³⁷⁸ Given the current shortcomings and pitfalls of PROMs, it is premature for the FDA and CMS to make them mandatory. The agencies should continue to work with experts to produce PROM guidance for regulated entities so that PROMs that are used voluntarily provide sound data.³⁷⁹

In addition, the FDA should continue to scrutinize any PROMs that are used to meet regulatory requirements and to provide assessments as to whether they are "fit-for-purpose."³⁸⁰ CMS would be wise to undertake a similar review and approval process for any PROMs it accepts for payment programs. Note that a determination that a PROM is fit for purposes of FDA or CMS determinations will not necessarily mean that it is also an appropriate choice for clinical care.

4. Financial Incentives

Both the federal government and private insurers can institute financial incentive programs to promote PROM adoption. This section posits that a government program akin to the one established for electronic health records is

³⁷⁴ 45 C.F.R. § 164.520(a) (2022).

³⁷⁵ American Medical Association, *Electronic Communication with Patients*, <https://www.ama-assn.org/delivering-care/ethics/electronic-communication-patients> (last visited Dec. 11, 2022).

³⁷⁶ *Id.*

³⁷⁷ Anne Johnson, Jayne Sandford & Jessica Tyndall, *Written and Verbal Information Versus Verbal Information Only for Patients Being Discharged from Acute Hospital Settings to Home*, 4 COCHRANE DATABASE SYSTEMATIC REV., Art. No.: CD003716. DOI: 10.1002/14651858.CD003716 (2003), p. 2 (recommending that patients be given both written and verbal instructions).

³⁷⁸ See *supra* notes 257-266 and 281-287 and accompanying text.

³⁷⁹ See *supra* notes 261, 272-275, and 285 and accompanying text (listing several existing and developing guidance documents).

³⁸⁰ See *supra* notes 266-267 and accompanying text.

unlikely. Private insurers, however, may well opt to pay providers bonuses for PROM use, though they should not penalize providers for deficient PROM scores at this time.

a. Government Incentives

In order to accelerate the adoption of PROMs, Congress could pass legislation that establishes a federal incentives program and regulations for PROM adoption. This approach would follow the precedent set by the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009.³⁸¹ The statute dedicated \$27 billion to the promotion of health information technology. The funding was used to award generous incentive payments to providers who adopted certified electronic health record systems and met regulatory specifications for their use.³⁸² In conjunction with the HITECH Act, CMS enacted the Meaningful Use regulations that detailed objectives that clinicians had to meet with respect to electronic health record system operation in order to receive payments.³⁸³ In addition, it established a process for the certification of electronic health record systems.³⁸⁴

Congress could adopt the same approach with respect to PROMs.³⁸⁵ It could enact legislation that empowered CMS to establish a financial incentive program along with regulations for PROM implementation. PROMs would be certified if they met particular requirements such as those outlined above. Providers who work with Medicare and Medicaid patients could receive payments to offset PROM-related investments of time and money. CMS regulations would strive to ensure that providers not only collect suitable PROM data but also employ them to improve patient care.

A PROMs incentive program, however, is improbable. First, such an initiative would require an investment of billions of dollars,³⁸⁶ and PROMs implementation is unlikely to be a high priority for Congress in this divisive and crisis-prone era. Second, it is doubtful that clinicians who are already overburdened will be receptive to additional regulatory requirements, even if they are accompanied by incentive payments. The meaningful use regulations were widely criticized and resented.³⁸⁷

³⁸¹ Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. No. 111-15, 123 Stat. 226 (2009) (codified as amended in scattered sections of 42 U.S.C.).

³⁸² SHARONA HOFFMAN, ELECTRONIC HEALTH RECORDS AND MEDICAL BIG DATA 2 (2016). Eligible professionals could receive up to \$43,720 from Medicare and up to \$63,750 from Medicaid. *Id.* at 39.

³⁸³ *Id.* at 42-46; 42 C.F.R. §§ 495.2-495.370 (2022).

³⁸⁴ HOFFMAN, *supra* note 382, at 46-49; 45 C.F.R. § 170.314 (2022).

³⁸⁵ See NATIONAL QUALITY FORUM, *supra* note 7, at 23; Wu et al., *supra* note 249, at 1869.

³⁸⁶ See *supra* note 382 and accompanying text.

³⁸⁷ HOFFMAN, *supra* note 382, at 49-50 (noting that some clinicians called the regulations the “meaningless abuse” regulations); Srinivas Emani, David Y. Ting, Michael Healey, Stuart R. Lipsitz, Andrew S. Karson & David W. Bates, *Physician Beliefs about the Meaningful Use of the Electronic Health Record: A Follow-Up Study*, 8 APPLIED CLIN. INFORMATICS 1044, 1050 (2017)

PROMs regulations are likely to receive a similar reception. Health care providers would be even more resentful of regulatory mandates that are not accompanied by financial payments to compensate for PROM implementation costs. At this time, CPGs and government agency guidelines may remain the better option.

b. Private Payer Incentives

Alternatively, private payers could offer health care providers financial incentives to implement PROMs. This could be an attractive option for payers that believe PROMs can improve health outcomes and save costs.³⁸⁸ As discussed above, BCBSMA already piloted such an incentive program.³⁸⁹

BCBSMA paid providers for participating in the PROMs initiative but did not adjust insurance coverage based on PROM data.³⁹⁰ This policy encouraged PROM adoption because it did not create any risk of penalty for providers, even if their patients' PROM scores appeared unfavorable. Given the many existing challenges of PROM implementation, this is a prudent approach.

It is important to understand that financial incentives for PROM adoption alone do not guarantee that PROMs will be collected consistently or used effectively to promote health care improvements. A 2020 study found that incentives increased PROM collection but did not necessarily lead to successful PROM programs.³⁹¹ Successful clinics were defined as those with a “mean collection rate in the 6 months prior to January 2019 [that] was 50% or greater.”³⁹² According to the study, health care organizations are most likely to be successful if they engage physicians in building enthusiasm for the benefits of PROMs and provide training regarding PROM use.³⁹³ Physician enthusiasm will likely depend on how cumbersome PROM review is and on the availability of tools such as AI that facilitate PROM use. Nevertheless, if employed in conjunction with some of the strategies described above, monetary inducements can play a useful role in encouraging clinicians to embrace PROMs and build a productive PROMs program.

VI.

CONCLUSION

PROMs hold promise as an emerging clinical tool that can also contribute to research, health care administration, and regulation. As other scholars have noted,

(“Only a fifth of the physicians responding to our survey agreed or strongly agreed that the meaningful use of the EHR would improve patient-centered care and the quality of care.”).

³⁸⁸ See *supra* notes 72-82 and 297-299 and accompanying text (discussing medical benefits and cost savings associated with PROMs).

³⁸⁹ See *supra* notes 288-299 and accompanying text.

³⁹⁰ See *supra* notes 292-294 and accompanying text.

³⁹¹ Sisodia et al., *supra* note 63, at 1.

³⁹² *Id.* at 3.

³⁹³ *Id.* at 6.

PROMs “directly support the primary goal of much of health care: to improve health-related quality of life,” because “[n]o one can judge this better than the patient.”³⁹⁴ The emergence of PROMS is particularly timely because physicians have ever-shrinking amounts of time to collect data from patients in face-to-face visits.

But PROMs currently have significant pitfalls, and their implementation is complex. This Article has argued that providers should be keenly aware of medical malpractice risks associated with PROMs and that the HIPAA Privacy Rule’s minimum necessary provision should be revised to address PROMs specifically. It further posits that it would be premature for the FDA, CMS, or private insurers to require PROM submission at this time.

Many strategies can be employed to strengthen PROMs and facilitate their integration into clinical practice and other arenas. These include clinical practice guidelines, patient education, financial incentives, PROM analysis by AI, stakeholder input, pilot programs, psychometric evaluations, and a variety of other safeguards relating to PROM selection and implementation. It remains to be seen whether PROMs can become a consistently reliable tool for clinicians, researchers, and others. But with careful planning and execution by qualified experts, PROMs may be able to fulfill their promise of serving as an important instrument to promote health care delivery improvements and bolster efforts to control medical costs.

³⁹⁴ Wu et al., *supra* note 249, at 1864.