# SUMMARY OF CHANGES TO THE 2024 LEAPFROG ASC SURVEY AND RESPONSES TO PUBLIC COMMENTS

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Through participation in the Leapfrog ASC Survey, and by extension the public comment process, ambulatory surgery centers (ASCs) continue to demonstrate their commitment to transparency and empower employers and purchasers to find the highest-value care while giving consumers the lifesaving information they need to make informed decisions. Hospital and ASC Survey Results are <u>publicly reported</u> so stakeholders can compare hospital outpatient departments (HOPDs) and ASCs side-by-side. Participating ASCs are also eligible for consideration for awards programs including the Money.com list of <u>Best Surgery Centers</u> and the <u>Leapfrog Top ASCs</u> designation.

Since the inaugural launch of the Leapfrog Ambulatory Surgery Center (ASC) Survey in 2019, Leapfrog has worked with ASCs, its Board of Directors, <u>Regional Leaders</u>, our <u>national expert panel</u>, the research faculty at Johns Hopkins Medicine, and purchaser members to develop Survey content. We also work with and rely upon our <u>Ambulatory Surgery Center</u> <u>Advisory Committee</u>, launched in March 2022, to advise on key issues related to ASC safety, quality, and efficiency.

Leapfrog's scientific experts review the latest evidence and literature to refine the current measures included in the Survey and propose changes for each upcoming year. We then seek public comment on the proposed changes and use stakeholder feedback to finalize the Survey content.

We are grateful to those who take the time to submit comments each year. These comments bring enormous value to Leapfrog's team and help ensure the Survey is valuable to ASCs, purchasers, and consumers. These comments, as well as results from the pilot test, are incorporated into the final ASC Survey and scoring algorithms. A final summary of changes and a summary of public comments and <u>responses to public comments</u> are included in this document.

The 2024 Leapfrog ASC Survey will open on April 1 and a PDF of the Survey will be available for download on the <u>Leapfrog</u> <u>ASC Survey webpage</u>. ASCs and other stakeholders interested in learning more and participating in the 2024 Leapfrog ASC Survey can register to attend free informational sessions on the Town Hall Calls <u>webpage</u>.

### **DEADLINES AND REPORTING PERIODS FOR 2024**

Review the 2024 Leapfrog ASC Survey deadlines and reporting periods in <u>Appendix I</u> and <u>Appendix II</u>. As a reminder, ASCs that do not submit a Survey by June 30 will be publicly reported as "Declined to Respond" until a Survey has been submitted.

### ON-SITE DATA VERIFICATION

Since the onset of the COVID-19 public health emergency in 2020, Leapfrog has performed its On-Site Data Verification virtually. We are pleased to <u>announce</u> the return of in-person visits in 2024 with a new partner, MetaStar.

MetaStar is a nonprofit organization based in Wisconsin with a wide breadth of experience and accomplishment in external quality review, healthcare quality consulting, and performance measurement. MetaStar works with organizations such as the CDC, CMS, and the Wisconsin Department of Health Services and is also a part of the Superior Health Quality Alliance, a Quality Innovation Network working on quality improvement for Medicare beneficiaries. MetaStar has worked with a variety of facilities over the last 50 years, including hospitals and ambulatory surgery centers, and brings valuable expertise to support Leapfrog in its on-site data verification efforts.

On-Site Data Verification builds on Leapfrog's robust protocols for verifying Survey responses submitted via the Leapfrog Hospital and ASC Surveys. Hospitals and ASCs that participated in the 2023 Surveys will be eligible for On-Site Data



Verification in 2024. Facilities selected for On-site Data Verification will be contacted by MetaStar in June 2024. Scheduled half-day visits will take place in September and October 2024.

### SUMMARY OF CONTENT AND SCORING CHANGES

### ASC PROFILE

There are no changes to the ASC Profile.

### SECTION 1: PATIENT RIGHTS AND ETHICS

Leapfrog is changing the name of Section 1: Basic Facility Information to *Patient Rights and Ethics* to reflect the content of the section more accurately. The newly named section includes the following subsections:

1A: Basic Facility Information

**1B: Billing Ethics** 

1C: Health Care Equity

### SECTION 1A: BASIC FACILITY INFORMATION

Leapfrog is removing the optional, fact-finding question on how ASCs are integrating environmental services and facilities engineering into their quality and safety structures. Leapfrog continues to work with experts and partners to explore the development of a new standard around environmental hygiene.

Leapfrog added a new required question on the facility's process for following-up on patient-reported concerns. This question will not be scored but will be publicly reported. The new question is available in <u>Appendix III.</u>

There are no other changes to the public reporting of information in Section 1A: Basic Facility Information.

### SECTION 1B: BILLING ETHICS

In response to feedback received from ASCs participating in the Survey, an analysis of responses submitted to the 2023 Leapfrog ASC Survey, and new insights from researchers in the field, Leapfrog is making the following updates to Section 1B: Billing Ethics:

- This subsection will now concentrate on billing ethics exclusively and was renamed Section 1B: Billing Ethics. The Health Care Equity questions were moved to Section 1C.
- Question #1, regarding the itemized billing statement, was updated to clarify that facilities can provide the required information to patients by mail or electronically (via email or the patient portal). We have also added a clarification that information about providing financial assistance need only be included if applicable.
- Question #4, regarding the quantified analysis of billing representatives' response times, was removed.
- Question #5, regarding taking legal action against patients for late or insufficient payment of a medical bill, will
  include a new response option for Military Treatment Facilities who are required by federal law to turn delinquent
  debt over to a federal agency.



The updated questions are included in Appendix IV.

### SECTION 1C: HEALTH CARE EQUITY

After three years of fact-finding and based on an analysis of responses submitted to the 2022 and 2023 Surveys, Leapfrog is scoring and publicly reporting both hospital and ambulatory surgery center performance on a set of health care equity questions focused on: (1) the collection of patient self-reported demographic data, (2) staff training on best practices for collecting those data, (3) stratifying quality and safety measures by patient self-reported demographic data, and (4) efforts to identify disparities and address any that are found. Our goal in scoring and publicly reporting performance in 2024 is to continue to urge hospitals and ambulatory surgery centers to address health care equity by implementing the fundamental practices and protocols captured in the question set. Our hope is to further advance this new standard over time as new research emerges on best practices to ensure that all patients receive safe, high-quality care.

The updated questions and scoring algorithm are available in Appendix V.

### SECTION 2: MEDICAL, SURGICAL, AND CLINICAL STAFF

We are removing the additional requirement to have a physician or CRNA present until all patients have been physically discharged from the building. ASCs will only be scored on whether they ensure an ACLS/PALS trained clinician, as well as a second clinician (regardless of ACLS/PALS training) are present at all times and immediately available in the building while an adult/pediatric patient is present in the facility.

The updated questions and scoring algorithm are available in Appendix VI.

### SECTION 3: VOLUME AND SAFETY OF PROCEDURES

### SECTION 3A: VOLUME OF PROCEDURES

Following an analysis of facility volume in 2023, Leapfrog is removing the following procedures due to the procedures not being widely performed in ASCs or HOPDs:

- Gastroenterology: Adult Other Upper GI Procedures; Pediatric Upper and Lower GI Endoscopy and Other Upper GI Procedures
- General Surgery: Pediatric Inguinal and Femoral Hernia Repairs and Other Hernia Repairs
- Ophthalmology: Pediatric Anterior and Posterior Segment Eye Procedures

### SECTION 3B: FACILITY AND SURGEON VOLUME

In 2024, ASCs that perform bariatric surgery for weight loss procedures will be scored and publicly reported for the first time based on whether they meet Leapfrog's minimum facility volume standard of 50 and whether the facility's process for privileging its surgeons includes meeting or exceeding the minimum surgeon volume standard of 20. The scoring algorithm is available below.



Facility and Surgeon Volume Standard Score (Performance Category)	Meaning that
Achieved the Standard (4 bars)	<ul> <li>The facility <u>met</u> the minimum facility volume standard for the procedure (50); and</li> <li>The facility's process for privileging surgeons <u>does</u> include meeting or exceeding the minimum surgeon volume standard (20).</li> </ul>
Considerable Achievement (3 bars)	<ul> <li>The facility <u>met</u> the minimum facility volume standard for the procedure (50); <b>but</b></li> <li>The facility's process for privileging surgeons <u>does not</u> include meeting or exceeding the minimum surgeon volume standard (20).</li> </ul>
Some Achievement (2 bars)	<ul> <li>The facility <u>did not meet</u> the minimum facility volume standard for the procedure (50), <b>but</b></li> <li>The facility's process for privileging surgeons <u>does</u> include meeting or exceeding the minimum surgeon volume standard (20).</li> </ul>
Limited Achievement (1 bar)	<ul> <li>The facility <u>did not meet</u> the minimum facility volume standard for the procedure (50); and</li> <li>The facility <u>does not</u> include the minimum surgeon volume standard in its privileging process (20).</li> </ul>
Does Not Apply	The facility does not perform the procedure.

Leapfrog is also adding four diagnosis codes to bariatric surgery for weight loss to identify cases done explicitly for weight loss purposes.

ICD-10 Diagnosis Code	Code Description
E66.1	Drug induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation
E66.3	Overweight
E66.9	Obesity, unspecified

Finally, Leapfrog is removing the surgical appropriateness questions. This question set was originally developed as part of Leapfrog's facility and surgeon volume standards, to address concerns about surgical overutilization, a well-established problem recounted in research, and a top concern of purchasers, employers, and payors. To-date, responses to these questions have not been scored, but have been used in public reporting. However, after several years of data collection and analysis it remains unclear whether the questions in Subsection 3B are effectively addressing surgical overuse, and therefore we will remove them. We will examine new approaches for identifying and measuring surgical overuse and welcome feedback from facilities on alternative measures.

### SECTION 3C: PATIENT SELECTION AND PATIENT FOLLOW-UP

### PATIENT SELECTION

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Leapfrog is removing questions on the types of patient screenings performed at hospitals and ASCs prior to scheduled outpatient surgery. Analysis of Survey results over several years finds minimal variation in responses among facilities. To date, responses to these questions have not been scored but have been used in public reporting. With this change, the responses will be removed from public reporting. Leapfrog will evaluate restoring this measure if and when variations in patient screening criteria emerge among facilities, especially as outpatient procedures become longer and more complex.

### PATIENT FOLLOW-UP

There are no changes to these questions.

Leapfrog obtains data for three CMS Ambulatory Surgical Center Quality Reporting (ASCQR) measures directly from CMS' website:

- ASC-12: Rate of Unplanned Hospital Visits After an Outpatient Colonoscopy
- ASC-17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures
- ASC-18: Hospital Visits After Urology Ambulatory Surgical Center Procedures

In order for Leapfrog to obtain the data for each applicable ASCQR measure, facilities must provide a valid CMS Certification Number (CCN) and National Provider Identifier (NPI) in the Profile Section of the Online Survey Tool and submit the Leapfrog ASC Survey.

Facilities that do not perform applicable procedures will be scored and publicly reported as "Does Not Apply." Facilities that do not provide an accurate CCN and NPI in the Profile or do not report applicable data to CMS will be scored and publicly reported as "Unable to Calculate Score." Facilities that do not submit a Leapfrog ASC Survey will be scored and publicly reported as "Declined to Respond."

CMS data will be scored and publicly reported for ASCs that have submitted a Survey by	CMS Reporting Period	Available on ASC Details Page	Available on the Public Reporting Website
June 30, 2024	ASC-12: Most recent 36 months ASC-17: Most recent 24 months ASC-18: Most recent 24 months	July 12, 2024	July 25, 2024
August 31, 2024	ASC-12: Most recent 36 months ASC-17: Most recent 24 months ASC-18: Most recent 24 months	September 9, 2024	September 9, 2024
November 30, 2024	ASC-12: Most recent 36 months ASC-17: Most recent 24 months ASC-18: Most recent 24 months	December 6, 2024	December 6, 2024



Data will be downloaded from the CMS provider catalog at <u>https://data.cms.gov/provider-data/dataset/4jcv-atw7.</u>

### SECTION 3D: INFORMED CONSENT

In response to feedback from facilities participating in the Survey, an analysis of responses submitted in 2023, and close consultation with our <u>Patient and Family Caregiver Expert Panel</u>, Leapfrog is making the following updates to Section 3D: Informed Consent:

- We are narrowing the focus of the Informed Consent Standard from <u>all</u> tests, treatments, and procedures, to <u>ONLY</u> those procedures where general and regional anesthesia is used, or where monitored anesthesia care is administered. This update is reflected in Important Note 1 prior to the questions, and the question text has been updated to clarify as well. The anesthesia consent process and consent forms continue to be excluded from Leapfrog's standard.
- We are adding a new response option to question #5, regarding the reading level of applicable consent forms, to account for consent forms written at a 9th grade reading level or lower.
- Question #5, regarding the availability of the medical interpreter, is being updated to clarify that when needed, the patient/legal guardian has access to a qualified medical interpreter, NOT a family caregiver.
- Question #14, regarding the solicitation of feedback from patients/legal guardians about the informed consent process, which was optional and for fact-finding in 2023, is moving to the set of required questions, but will not be used in scoring and public reporting.
- Optional, fact-finding questions #7-13, and 15, concerning additional aspects of the informed consent process were removed.
- We updated the FAQs as follows:
  - FAQ #28, which recommends a method for assessing the reading level of the consent form, was updated to include the <u>SMOG readability measure</u>, and to indicate that Readable.com and other similar online tools that use either the Flesch-Kincaid or SMOG readability standard to evaluate the readability of written language are appropriate tools for assessing consent forms.
  - A new FAQ was added to clarify that information intended to be read by the provider, information that is written in by an individual provider to give that patient information specific to their condition, and any words where a sixth-grade reading level definition is included with the term can be excluded from the reading level assessment.
  - A new FAQ was added to clarify that assistants and trainees do not need to be named on the consent form.
  - A new FAQ was added to define a qualified medical interpreter.
  - A new FAQ was added on the solicitation of feedback from patients.

Leapfrog would like to extend special gratitude to the many commenters who offered their perspectives on the reading level element of Leapfrog's Informed Consent Standard, and detailed explanations of the impact of the standard on surgery centers in states like Texas, where optional consent form language is provided by the state. The scoring algorithm is being updated to account for the new response option to Question #5 described above, where surgery centers reporting that all applicable consent forms are written at a 9th grade reading level or lower will be able to earn more credit than they could in the 2023 Survey, up to "Considerable Achievement," if additional criteria are met as well. However, because 54% of Americans between the ages of 16 and 74 read below the equivalent of a sixth-grade level, surgery centers will continue to



be required to have all applicable consent forms written at a 6th grade reading level or lower to "Achieve the Standard." The updated questions, new FAQ, and new scoring algorithm are included in <u>Appendix VII</u>.

### SECTION 3E: SAFE SURGERY CHECKLIST FOR ADULT AND PEDIATRIC OUTPATIENT PROCEDURES

Leapfrog is making three updates to Section 3E: Safe Surgery Checklist for Adult and Pediatric Outpatient Procedures.

First, Leapfrog is updating the reporting period for Section 3E: Safe Surgery Checklist for Adult and Pediatric Outpatient Procedures from 3 months to 12 months. This will align with the reporting period for Section 3A: Volume of Procedures and 3B: Facility and Surgeon Volume. Facilities should continue to sample patients who had a procedure performed in Section 3A and/or 3B in the 12 months prior to Survey submission if performing retrospective audits of medical records or other EHR data. Otherwise, facilities may perform in-person observational audits throughout the reporting period.

Second, we are adding a new question asking facilities to report the sample size for their Section 3E audits. This question will only be used as part of Leapfrog's <u>Data Verification Protocols</u>.

Finally, Leapfrog is updating the pre-anesthesia checklist to clarify that the availability of devices on-site element only applies to endoscopy procedures to align with the <u>AHRQ Endoscopy Checklist</u>.

There are no changes to the scoring algorithm for Section 3E: Safe Surgery Checklist for Adult and Pediatric Outpatient Procedures.

### SECTION 4: PATIENT SAFETY PRACTICES

### SECTION 4A: MEDICATION SAFETY

### MEDICATION AND ALLERGY DOCUMENTATION

Leapfrog will clarify that only medications newly prescribed at discharge should be counted as medications prescribed at discharge **and** administered during the visit in question #5. This is a clarification from the previous "and/or" language.

Leapfrog will also add medications prescribed for the purpose of operative preparation prior to a colonoscopy to the list of excluded medications.

There are no changes to the scoring algorithm for Section 4A: Medication Safety.

### SECTION 4B: NHSN OUTPATIENT PROCEDURE COMPONENT MODULE

There are no changes to this subsection.

Ambulatory surgical centers (ASCs) are required to join Leapfrog's NHSN Group for ASCs for Leapfrog to download data on the following measures included in Section 4B NHSN Outpatient Procedure Module of the 2024 Leapfrog ASC Survey:

- Same day outcome measures: patient burns, falls, "wrong" event, and all-cause hospital transfer/admission.
- Surgical site infections for Infections for breast surgery (BRST), laminectomy (LAM), herniorrhaphy (HER), and knee prosthesis (KPRO) using an All-SSI SIR model.



Leapfrog will also download a copy of your facility's 2023 Outpatient Procedure Component (OPC) Ambulatory Surgery Center (ASC) Annual Facility Survey.

Data will be available on the ASCs Details Page, as well as scored and publicly reported by Leapfrog for facilities that:

- 1. Join Leapfrog's NHSN Group for ASCs by the dates below
- 2. Submit SDOM and SSI Monthly Reporting Plans and applicable Summary Data,
- 3. Enter a valid NHSN ID in the Profile Section of their 2024 Leapfrog ASC Survey,

Complete, affirm, and submit the 2024 Leapfrog ASC Survey by the dates below:

Join Leapfrog's NSHN Group by	Leapfrog will download data from NHSN for all current group members	Data downloaded from NHSN will be scored and publicly reported for ASCs that have submitted a Survey by	SDOM and SSI Reporting Period	Available on ASC Details Page and Public Reporting Website
June 20, 2024	June 21, 2024	June 30, 2024	Latest 6 months prior to Survey submission	July 12, 2024 Details Page July 25, 2024 Public Reporting Website
August 22, 2024	August 23, 2024	August 31, 2024	Latest 6 months prior to Survey submission	September 9, 2024*
October 23, 2024	October 24, 2024	October 31, 2024	Latest 6 months prior to Survey submission	November 7, 2024*
December 18, 2024	December 19, 2024**	November 30, 2024	Latest 6 months prior to Survey submission	January 8, 2025*

Leapfrog will provide step-by-step instructions for ASCs to download the same reports that Leapfrog downloads for each of the NHSN data downloads on our <u>website</u> by April 1.

\* Available on ASC Details Page on the same date as public release of Survey Results

\*\* The Leapfrog ASC Survey closes on November 30, 2024. The last NHSN data download is on December 19, 2024 to incorporate any ASCs and corrections from ASCs that joined by the last join date of December 18, 2024.

### SECTION 4C: HAND HYGIENE

Leapfrog is removing question #22 which asks about the accessibility of sinks for hand washing. This question has not been used in scoring or public reporting.

There are no changes to the remaining questions or the scoring algorithm for Section 4C: Hand Hygiene.

### SECTION 4D: NATIONAL QUALITY FORUM (NQF) SAFE PRACTICES

### NQF SAFE PRACTICE #1 - CULTURE OF SAFETY LEADERSHIP STRUCTURES AND SYSTEMS

There are no changes to these questions.

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### NQF SAFE PRACTICE #2 - CULTURE MEASUREMENT, FEEDBACK, AND INTERVENTION

There are no changes to these questions.

NQF SAFE PRACTICE #4 - RISKS AND HAZARDS

There are no changes to these questions.

### SECTION 4E: NEVER EVENTS

There are no changes to this subsection.

### SECTION 4F: NURSING WORKFORCE

There are no changes to this subsection.

### SECTION 5: PATIENT EXPERIENCE (OAS CAHPS)

There are no changes to this section.



More information about the 2024 Leapfrog ASC Survey is available on our website at

www.leapfroggroup.org/ASC.



### **RESPONSES TO PUBLIC COMMENTS**

Leapfrog was grateful to receive several valuable public comments in response to the proposed changes to the 2024 Leapfrog ASC Survey and through the national pilot test of the 2024 Leapfrog ASC Survey. Comments were submitted from health care organizations, as well as health care experts, patient advocates, and purchasers.

If you submitted a comment and do not see a response, or if you have additional questions, please contact the Help Desk at <a href="https://leapfroghelpdesk.zendesk.com">https://leapfroghelpdesk.zendesk.com</a>. Comments are extremely helpful to the development of high-quality Surveys, and we thank commenters for their insights.

### SECTION 1: PATIENT RIGHTS AND ETHICS

### BASIC FACILITY INFORMATION

One commenter supported the removal of the fact-finding question which assessed the integration of environmental services and facilities engineering into quality and safety structures.

We appreciate this feedback.

### HEALTH CARE EQUITY

One commenter supported Leapfrog's Health Care Equity standard but noted there may be differences among ASCs based on ownership structure, particularly among independently owned ASCs where surgeons choose the patients. Similarly, another commenter requested separate scoring criteria between non-hospital owned ASCs, hospital owned ASCs and hospital outpatient departments (HOPDs).

We appreciate this feedback, but strongly believe that all surgery centers should be held to the same standard regarding improving health care equity. Further, three years of fact-finding indicate that many ASCs, regardless of ownership, are already implementing the best practices outlined in the questions. We will closely monitor performance now that the questions will be scored and publicly reported, and if additional updates to scoring are required to ensure comparability, we will propose those changes for future Surveys.

One commenter supported Leapfrog's Health Care Equity standard but noted that the question set does not address other factors such as structural or cultural barriers, available resources, organizational policies and procedure, access to services and fee structure. They encouraged Leapfrog to report a holistic view of an organization.

Leapfrog recognizes there are many levers to combat disparities in health care. However, Leapfrog's focus for this first of its kind national standard is on ASC efforts to reduce differences in outcomes for their patients based on race, ethnicity, and language.

# One commenter cautioned Leapfrog against including the Health Equity Standard on the Leapfrog ASC Survey since many hospitals are not yet implementing these practices.

Thank you for this feedback. Leapfrog has included questions about health care equity on the Leapfrog ASC Survey for three years, giving ambulatory surgery centers (ASCs) ample time to familiarize themselves with the requirements and found that more than half of reporting ASCs were collecting patient self-reported demographic data and training staff responsible for collecting those data, and almost one-third stratifying at least one quality measure. However, Leapfrog recognizes ASCs

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provide a different level of care from hospitals, with patients being discharged the same day of their procedure, therefore, we have developed a slightly different set of criteria for scoring ASCs on the Health Care Equity standard.

#### SECTION 2: MEDICAL, SURGICAL AND CLINICAL STAFF

#### No comments were submitted.

### SECTION 3: VOLUME AND SAFETY OF PROCEDURES

### **VOLUME OF PROCEDURES**

Leapfrog received several comments in support of removing procedures where low or no volume was being reported.

We appreciate this feedback.

### FACILITY AND SURGEON VOLUME

Several commenters supported scoring and publicly reporting bariatric surgery for weight loss.

We appreciate this feedback.

Many comments were in support of the removal of the surgical appropriateness question set.

We appreciate this feedback.

# One commenter expressed concerns about publicly reporting information on facility and surgeon volumes, noting that they believe rural or solo practices and new or growing practices may have difficulty meeting the minimum volume standards.

The three procedures included in this section have a strong evidence-based relationship between volume and patient outcomes, and Leapfrog believes it is vital to provide this information to the public. Three decades of research have consistently demonstrated that patients that have their high-risk surgery at a facility and by a surgeon that have more experience with the procedure have better outcomes, lower complication rates, and a shorter length of stay than for patients who have their surgery done at a facility or by a surgeon with less experience. Leapfrog's goal with establishing surgeon volume standards is to ensure that facilities are not putting patients at increased risk by allowing low-volume surgeons to perform these high-risk surgeries. The surgeon volume standards Leapfrog is currently using are either based on the volume-outcome literature and/or align with national society recommendations. This information is all provided in our fact sheet, which includes a bibliography.

At the same time, Leapfrog does not wish to put new or growing facilities at a disadvantage, thus Leapfrog provides a grace period for new practices, surgeons, or service lines:

- 1. 18-month grace period before reporting on a new service line.
- 2. 24-month grace period before reporting on new surgeons who have just finished their training.



Leapfrog also gives ASCs the option to report on a 24-month annual average to accommodate for any fluctuations in facility volume. And when determining if a surgeon meets the minimum volume standard, we expect all cases to be counted, including those performed at other facilities. We also allow diagnosis codes to be ignored when counting surgeon volume.

Additionally, if a surgeon was absent for an extended time during the reporting period, the procedures performed by this surgeon during the reporting period should still be counted towards the ASC's procedure total. However, the surgeon would not need to be considered when responding to questions regarding whether your ASC's process for privileging includes the surgeon having to meet Leapfrog's minimum annual surgeon volume standards until they have been active again for an entire reporting period (likely the next year).

All of the information above is provided in the specifications and FAQs in the hard copy of the Survey available here: <a href="https://www.leapfroggroup.org/asc-survey-materials/survey-materials">https://www.leapfroggroup.org/asc-survey-materials/survey-materials</a>.

### PATIENT SELECTION

No comments were submitted.

### PATIENT FOLLOW-UP

No comments were submitted.

### **INFORMED CONSENT**

Some commenters supported the proposed updates to the informed consent section. We appreciate this feedback.

# Several commenters requested that Leapfrog wait an additional year before adding the question (question #2) regarding solicitation of feedback from patients on the informed consent process to scoring and publicly reporting and requested additional clarification on appropriate methods to solicit feedback from patients.

Based on the feedback collected during the public comment period and through the pilot, Leapfrog has decided to wait an additional year before including the question regarding soliciting feedback from patients on the informed consent process in scoring and public reporting. The question will still be required, and responses will be used to inform an eventual scoring approach in subsequent years of the ASC Survey. Leapfrog has also added an FAQ to provide examples of methods for soliciting feedback from patients on their consent process, or specific questions to ask patients.

# Some commenters requested additional clarification about when patients might choose to have a family member act as their interpreter.

To reduce confusion, Leapfrog has removed the question text that read "If anyone other than a qualified medical interpreter is ever used to translate (e.g., caregiver or family member), select 'No.'" The goal of the question is to ensure that, where needed, patients are provided access to a qualified medical interpreter, and family members are not relied on as translators. However, if a patient would prefer to use a family member as a translator, they may do so, and facilities are encouraged to recognize that choice.



Several commenters expressed concern about holding surgery centers in Texas accountable for ensuring their consent forms are at a 6th grade reading level, given that the state's recommended consent template is at a 9th grade reading level. Other commenters supported a common national standard.

Leapfrog would like to extend special gratitude to the many commenters who offered background and their perspectives on state-developed consent forms. Based on the significant feedback we received, we are updating the response options to the reading level question to give hospitals and ambulatory surgery centers the opportunity to earn "Considerable Achievement" if all applicable consent forms are written at a ninth-grade reading level and additional criteria are also met.

Although we recognize that the informed consent process involves much more than the form, the consent form itself is the durable permanent record of the process that the patient signs to indicate their consent to undergo their procedure and therefore should be readable by all patients. Roughly half of Americans cannot read at a sixth grade reading level, therefore creating a structural inequity in ASCs where consent forms are written beyond the patient's comprehension. We encourage surgery centers to advocate in their states for appropriate consent forms that are accessible to their patients.

# Some commenters suggested that surgery centers be allowed to exclude complex words from the reading level assessment if those words are defined within the text itself.

Leapfrog has updated the FAQ on the reading level assessment to indicate that this is an acceptable approach. For example, if a consent form included the phrase "administering anesthesia (putting you to sleep)," facilities could exclude "administering anesthesia" from the assessment of reading level.

### SAFE SURGERY CHECKLIST FOR ADULT AND PEDIATRIC OUTPATIENT PROCEDURES

#### One commenter wanted clarification on whether the extended reporting period impacted the number of required audits.

There is no change in the audit requirement for the Safe Surgery Checklist for Adult and Pediatric Outpatient Procedures. Facilities should continue to sample 30 patients who had one of the procedures included in Section 3A and/or 3B as applicable and measure and report adherence to the safe surgery checklist based on that sample, as noted in the measure specifications.

### SECTION 4: PATIENT SAFETY PRACTICES

### MEDICATION SAFETY

One commenter supported the proposed language clarification that only medications newly prescribed at discharge should be counted as medications prescribed at discharge and administered during the visit in question #5.

We appreciate the feedback.

### NHSN OUTPATIENT PROCEDURE COMPONENT MODULE

#### No comments were submitted.

HAND HYGIENE



One commenter supported the removal of the fact-finding question on the accessibility of sinks which helps reduce reporting burden on participating facilities.

We appreciate this feedback.

### NQF SAFE PRACTICES

No comments were submitted.

### **NEVER EVENTS**

No comments were submitted.

### NURSING WORKFORCE

No comments were submitted.

### SECTION 5: PATIENT EXPERIENCE

One commenter recommended removing the OAS CAHPS domain "Patients Recommending the Facility" from the Survey since this measure is not included in the CMS VBP program.

The CMS VBP Program does not apply to ASCs. The four OAS CAHPS domains included in the ASC Survey align with the domains publicly reported by CMS for ASCs (data.cms.gov/provider-data) and those collected in the Leapfrog Hospital Survey for hospital outpatient departments.



### APPENDIX I: TIMELINE FOR THE 2024 LEAPFROG ASC SURVEY

Date	Deadline
March	Summary of Changes to the 2024 Leapfrog ASC Survey and Responses to Public Comments will be
	available for download at <u>https://www.leapfroggroup.org/asc-survey-materials/survey-materials</u> .
April 1	2024 LEAPFROG ASC SURVEY LAUNCH:
	The hard copy of the 2024 Leapfrog ASC Survey and supporting materials are available for
	download on the <u>Survey Materials webpage</u> . The <u>Online ASC Survey Tool</u> is available.
June 20	FIRST NHSN GROUP DEADLINE
	ASCs that join Leapfrog's NHSN Group by June 20, provide a valid NHSN ID in the Profile, and
	submit the Leapfrog ASC Survey by June 30, will have data available prior to public reporting on
	their ASC Details Page starting on July 12. Results will be publicly reported on July 25.
June 30	SUBMISSION DEADLINE:
	ASCs that submit a Survey by June 30 will have their Leapfrog ASC Survey Results <u>publicly</u>
	reported starting on July 25.
	ASCs that do not submit a Survey by June 30 will be publicly reported as "Declined to Respond"
	until a Survey has been submitted.
July 12	ASC DETAILS PAGE AVAILABLE:
	The first set of Leapfrog ASC Survey Results, which reflect Surveys submitted by June 30, will be
	privately available for ASCs to view on July 12 via the ASC Details Page link on the Survey
	Dashboard. In addition, Leapfrog will send out its first round of monthly data verification emails
	and documentation requests.
July 25	ASC SURVEY RESULTS PUBLICLY AVAILABLE:
	The first set of Leapfrog ASC Survey Results, which reflect Surveys submitted by June 30 will be
	published on Leapfrog's public reporting website.
	ASCs that do not submit a Survey by June 30 will be publicly reported as "Declined to Respond"
	until a Survey has been submitted. After July, results are updated on the fifth business day of the
	month to reflect Surveys (re)submitted by the end of the previous month.
August 31	TOP ASC DEADLINE:
	ASCs that would like to be eligible to receive a Leapfrog Top ASC Award must submit a Survey by
	August 31. Facilities are encouraged to submit their Survey by June 30 in order to resolve any
	data entry or reporting errors identified by Leapfrog through its monthly data verification and
	documentation requests.
	Benchmarking Reports: ASCs that would like to receive a free Summary Report must submit a
	Survey by August 31. The free Summary Report will be emailed to each ASC's Administrator and
November 30	Primary Survey Contact in September. LATE SUBMISSION DEADLINE:
November 50	The 2024 Leapfrog ASC Survey will close to new submissions at 11:59 pm ET on November 30. No
	new Surveys can be submitted after this deadline.
	new Surveys can be submitted after tins deadline.
	Only ASCs that have submitted a Survey by November 30 will be able to log into the Online ASC
	Survey Tool to make corrections to previously submitted sections during the months of December
	and January. Survey updates reflecting a change in performance must be made prior to
	November 30. Performance updates made after November 30 will not be scored or publicly
	reported.
January 31	CORRECTIONS DEADLINE:



ASCs that need to make corrections to previously submitted 2024 Leapfrog ASC Surveys must make necessary updates and re-submit the entire Survey by January 31, 2025. ASCs will not be able to make changes or submit their Survey after this date.



# APPENDIX II: REPORTING PERIODS FOR THE 2024 LEAPFROG ASC SURVEY

	Survey Submitted <u>Prior</u> to September 1	Survey (Re)Submitted <u>On or After</u> September 1
Survey Section	Reporting Period	Reporting Period
1A Basic Facility Information	12 months ending 12/31/2023	12 months ending 06/30/2024
1B Billing Ethics	N/A	N/A
<b>1C</b> Health Care Equity	N/A	N/A
2 Medical, Surgical, and Clinical Staff	Latest 3 months prior to Survey submission	Latest 3 months prior to Survey submission
3A Volume of Procedures	12 months endi	ng 12/31/2023
<b>3B</b> Facility and Surgeon Volume	Volume: 12 months or 24 months ending 12/31/2023	Volume: 12 months or 24 months ending 06/30/2024
<b>3C</b> Patient Follow-up	Patient Follow-up: Latest 24 or 36 months prior to Survey submission	Patient Follow-up: Latest 24 or 36 months prior to Survey submission
3D Informed Consent	N/A	N/A
<b>3E</b> Safe Surgery Checklist	Latest 12 months prior to Survey submission	Latest 12 months prior to Survey submission
<b>4A</b> Medication and Allergy Documentation	12 months ending 12/31/2023	12 months ending 06/30/2024
<b>4B</b> NHSN Outpatient Procedure Component Module	Latest 6 months prior to Survey submission	Latest 6 months prior to Survey submission
4C Hand Hygiene	N/A	N/A
<b>4D</b> National Quality Forum (NQF) Safe Practices	Latest 12, or 24 months prior to Survey submission (see individual Safe Practice for specific reporting period)	Latest 12, or 24 months prior to Survey submission (see individual Safe Practice for specific reporting period)
4E Never Events Policy	N/A	N/A
4F Nursing Workforce	N/A	N/A
<b>5</b> Patient Experience (OAS CAHPS)	Latest 12 months prior to Survey submission	Latest 12 months prior to Survey submission



### APPENDIX III: PATIENT-REPORTED CONCERNS QUESTION

### Section 1A: Basic Facility Information – New question for 2024

1)	<ul> <li>Does your facility have a protocol to follow-up on patient-reported concerns about their care that includes all of the following elements:</li> <li>All patients and family caregivers are <u>notified</u> of at least one method to report concerns with their care;</li> <li>All patients and family caregivers who report a concern are <u>contacted</u> by a facility representative within 30 days of making the report; and</li> </ul>	o Yes o No
	<ul> <li>All concerns reported by patients and family caregivers are logged in an incident reporting system</li> </ul>	



### APPENDIX IV: BILLING ETHICS QUESTIONS

### Section 1B: Billing Ethics – Questions for 2024

### Updates highlighted in <mark>yellow</mark>.

1)	What pricing information is displayed on your facility's website for commonly performed procedures? Select all that apply.	Payer-specific negotiated charges Cash prices None of the above
2)	Webpage URL where payer-specific negotiated charges or cash prices are displayed for consumer	
3)	<ul> <li>Within 30 days of the final claims adjudication (or within 30 days from date of service for patients without insurance), does your facility provide every patient, either by mail or electronically (via email or the patient portal), with a billing statement and/or master itemized bill for facility services that includes ALL the following? <ul> <li>a. Name and address of the facility where billed services occurred</li> <li>b. Date(s) of service</li> <li>c. An individual line item for each service or bundle of services performed</li> <li>d. Description of services billed that accompanies each line item or bundle of services performed</li> <li>e. Amount of any principal, interest, or fees (e.g., late or processing fees), if applicable</li> <li>f. Amount of any adjustments to the bill (e.g., health plan payment or discounts), if applicable</li> <li>g. Amount of any payments already received (from the patient or any other party), if applicable</li> <li>h. Instructions in the patient's preferred language on how to obtain a written translation or oral interpretation of the bill</li> <li>j. Notification that physician services will be billed separately, if applicable</li> </ul> </li> <li><i>If any one of the elements above are only provided upon request, select "Only upon request." If any one of the elements above are not ever provided, select "No."</i></li> </ul>	Yes No Only upon request
4)	<ul> <li>Does your facility give patients instructions for contacting a billing representative with:</li> <li>access to an interpretation service to communicate in the patient's preferred language, and</li> <li>the authority to (a) initiate an investigation into errors on the bill, (b) offer a price adjustment or debt forgiveness based on facility policy, and (c) offer a payment plan do all of the following within 10</li> </ul>	Yes No



	business days of being contacted by the patient or patient representative?	
5)	Does your facility take legal action against patients for late payment or	
	insufficient payment of a medical bill?	
		Yes
	This question does not include patients with whom your facility has	No
	entered into a written agreement specifying <u>a good faith estimate</u> for a	No, but is required by federal law
	medical service.	to transfer delinquent payments
		to the Department of Treasury
	Only Military Treatment Facilities should select "No, but required by	for action.
	federal law to transfer delinquent payments to the Department of	
	Treasury for action."	



### APPENDIX V: HEALTH CARE EQUITY QUESTIONS AND SCORING ALGORITHM

### Section 1C: Health Care Equity – Questions for 2024

1)	Which of the following patient self-identified demographic data does your facility collect directly from its patients (or patient's legal guardian) prior to or while registering a patient for a facility visit? Select all that apply. If "none of the above," skip the remaining questions in Section 1C and continue to the Affirmation of Accuracy.	<ul> <li>Race</li> <li>Ethnicity</li> <li>Spoken language preferred for healthcare (patient or legal guardian)</li> <li>Written language preferred for healthcare (patient or legal guardian)</li> <li>Sexual orientation</li> <li>Gender identity</li> <li>None of the above</li> </ul>
2)	Does your facility train staff responsible for registering patients either in- person or over the phone on how to collect self-identified demographic data from its patients (or patient's legal guardian) at both: • the time of onboarding, and • annually thereafter?	Yes No
3)	Does your facility use the patient self-identified demographic data it collects directly from patients (or patient's legal guardian) in question #1 to stratify <u>any</u> quality measure(s) with the aim of identifying health care disparities?	Yes No
	If "no," skip questions #4-5 and continue to question #6.	
4)	By stratifying the quality measure(s) in question #3, has your facility identified any health care disparities among its patients? If "no, disparities were not identified" or "inadequate data available to determine if disparities exist," skip question #5 and continue to question #6.	Yes, disparities were identified No, disparities were not identified Inadequate data available to determine if disparities exist
5)	In the past 12 months, has your facility used the data and information obtained through question #4 to update or revise its policies or procedures?	
	OR In the past 12 months, has your facility developed a written action plan	Yes No
	that describes how it will address at least one of the health care disparities identified through question #4?	



6)	Does your facility share information on its efforts to identify and reduce health care disparities based on <i>race, ethnicity, spoken language</i> <i>preferred for healthcare (patient or legal guardian), written language</i> <i>preferred for healthcare (patient or legal guardian), sexual orientation, or</i> <i>gender identity</i> and the impact of those efforts on its public website?	Yes No
7)	Does your facility report out and discuss efforts related to identifying and addressing health care disparities with your facility's governance and leadership at least annually?	Yes No

### Section 1C: Health Care Equity – Scoring Algorithm for 2024

Health Care Equity Score (Performance Category)	Meaning that	
<ul> <li>The facility collects, at a minimum, patient self-reported race, and preferred written or spoken language data as described in #1,</li> <li>Trains staff responsible for registering patients as described in</li> <li>Uses the patient self-reported demographic data to stratify at quality measure as described in question #3,</li> <li>And either:         <ul> <li>Has updated a policy or procedure to address the disp developed a written action plan as described in question disparities were identified in question #4) OR</li> <li>Shares information about efforts to identify and reduc care disparities on its website as described in question OR</li> <li>Reports out and discusses efforts to reduce health car with the facility's leadership and governance as description #7.</li> </ul> </li> <li>Question #5 is not used in scoring for facilities that responded "No, disparities question #4.</li> </ul>		
Considerable Achievement (3 bars)	<ul> <li>The facility collects, at a minimum, patient self-reported race, or ethnicity, or preferred written or spoken language data as described in question #1,</li> <li>Trains staff responsible for registering patients as described in question #2,</li> <li>Uses the patient self-reported demographic data to stratify at least one quality measure as described in question #3,</li> <li>And either:         <ul> <li>Has updated a policy or procedure to address the disparity or developed a written action plan as described in question #5 (if disparities were identified in question #4) OR</li> </ul> </li> </ul>	



	<ul> <li>Shares information about efforts to identify and reduce health care disparities on its website as described in question #6 OR</li> <li>Reports out and discusses efforts to reduce health care disparities with the facility's leadership and governance as described in question #7.</li> <li>Question #5 is not used in scoring for facilities that responded "No, disparities were not identified" or "Inadequate data available to determine if disparities exist" to question #4.</li> </ul>	
Some Achievement (2 bars)	<ul> <li>The facility collects, at a minimum, patient self-reported race, ethnicity, and preferred written or spoken language data as described in question #1,</li> <li>Trains staff responsible for registering patients as described in question #2,</li> <li>Uses the patient self-reported demographic data to stratify at least one quality measure as described in question #3,</li> <li>But has not yet:         <ul> <li>Updated a policy or procedure to address the disparity or developed a written action plan as described in question #5 (if disparities were identified in question #4) OR</li> <li>Shared information about efforts to identify and reduce health care disparities on its website as described in question #6 OR</li> <li>Reported out and discusses efforts to reduce health care disparities with the facility's leadership and governance as described in question #7.</li> </ul> </li> <li>Question #5 is not used in scoring for facilities that responded "No, disparities were not identified" or "Inadequate data available to determine if disparities exist" to question #4.</li> </ul>	
Limited Achievement (1 bar)	The facility responded to all the questions in this section, but it does not yet meet the criteria for Some Achievement.	



### APPENDIX VI: MEDICAL, SURGICAL, AND CLINICAL STAFF QUESTIONS AND SCORING ALGORITHM

### Section 2: Medical, Surgical and Clinical Staff – Questions for 2024

1)	Is there an Advanced Cardiovascular Life Support (ACLS) trained clinician, as well as a second clinician (regardless of ACLS training), present at all times and immediately available in the building while an adult patient (13 years and older) is present in the facility? Facilities that did not perform any applicable procedures on patients 13 years and older during the reporting period should select "not applicable; pediatric patients only." These facilities will be scored as "Does Not Apply".	0 0 0	Yes No Not applicable; pediatric patients only
2)	Is there a Pediatric Advanced Life Support (PALS) trained clinician <b>Error!</b> <b>Bookmark not defined.</b> , as well as a second clinician (regardless of PALS training), present at all times and immediately available in the building while a pediatric patient (infant through 12 years) is present in the facility? <i>Facilities that did not perform any applicable procedures on pediatric patients (infant through 12 years) during the reporting period, regardless of the presence of clinicians trained in PALS, should select "not applicable; adult patients only." These facilities will be scored as "Does Not Apply"</i> .	0 0	Yes No Not applicable; adult patients only
3)	To help ensure that patients are cared for by well-trained physicians and anesthesia providers (e.g., anesthesiologists and certified registered nurse anesthetists), do your medical staff by-laws or facility-wide policies require all physicians and anesthesia providers who have privileges to provide care at your facility to be board certified or board eligible?	0	Yes No



### Section 2: Medical, Surgical and Clinical Staff – Scoring Algorithm for 2024

Certified Clinicians Present While Patients Are Recovering Score (Performance Category)	Meaning that	Meaning that
Achieved the Standard	While <b>adult</b> patients are recovering, the facility ensures that an ACLS trained clinician, as well as a second clinician (regardless of ACLS training), are present at all times and immediately available in the building while an adult patient (13 years and older) is present in the facility.	While <b>pediatric</b> patients are recovering, the facility ensures that a PALS trained clinician, as well as a second clinician (regardless of PALS training), are present at all times and immediately available in the building while a pediatric patient (infant through 12 years) is present in the facility.
Limited Achievement	While <u>adult</u> patients are recovering, an ACLS trained clinician, as well as a second clinician (regardless of ACLS training), are <u>NOT</u> present at all times and immediately available in the building while an adult patient (13 years and older) is present in the facility.	While <b>pediatric</b> patients are recovering, a PALS trained clinician, as well as a second clinician (regardless of PALS training), are <u>NOT</u> present at all times and immediately available in the building while a pediatric patient (infant through 12 years) is present in the facility.
Does Not Apply	The facility does not perform procedures on <u>adult p</u> atients.	The facility does not perform procedures on <b>pediatric</b> patients.



### APPENDIX VII: INFORMED CONSENT QUESTIONS, FAQS, AND SCORING ALGORITHM

### Section 3D: Informed Consent – Questions for 2024

Updates highlighted in yellow.

### **Policies and Training**

1)	<ul> <li>Does your facility have a training program on informed consent that tailors different training topics to <u>different staff roles</u>, including facility leaders, MD/NP/PA, nurses and other clinical staff, administrative staff, and interpreters, and has your facility made the training: <ul> <li>a required component of onboarding for the appropriate newly hired staff, and</li> <li>required for the appropriate existing staff who were not previously trained?</li> </ul> </li> </ul>	Yes No
2)	At least once a year, does your facility solicit feedback from patients/legal guardians about your facility's informed consent process to understand how it can be improved over time? This question is required but response will not be scored or publicly reported in 2024.	Yes No

### Content of Informed Consent Forms

<ul> <li>3) As part of your facility's process for obtaining informed consent, does:</li> <li>the clinician explain expected difficulties, recovery time, pain management, and restrictions after a procedure that may be experienced by the patient either in the facility or post-discharge, if applicable;</li> <li>the patient have the opportunity to ask questions; and</li> <li>the consent form document that these two elements of the process have taken place?</li> </ul>	Yes No
<ul> <li>4) Do ALL applicable consent forms used by your facility include:</li> <li>the name(s) of the clinician(s) performing the procedure,</li> <li>whether the clinician is expected to be absent from portions of the procedure (e.g., opening, closing), if applicable and</li> <li>whether any assistants or trainees will be involved in the procedure, if applicable?</li> </ul>	Yes No



Yes, all applicable forms are written at a 6th grade reading level or lower
Are ALL applicable consent forms used by your facility written at a 6<sup>th</sup> grade reading level or lower?
The procedure name and description, and any words accompanied by a plain language definition can be excluded from the reading level assessment.
Yes, all applicable forms are written at a 6th grade reading level or lower
No forms are written at a 6th grade reading level or lower
All forms are written at a 9<sup>th</sup> grade reading level

### Process for Gaining Informed Consent

5)	<ul> <li>Prior to the informed consent discussion, does your facility:</li> <li>ask what the patient/legal guardian's preferred language for medical decision-making is,</li> <li>where needed, provide the patient/legal guardian access to a qualified medical interpreter, NOT a family caregiver,</li> <li>use a consent form or notation in the medical record to document whether a qualified medical interpreter was used to conduct the informed consent process, and</li> <li>have the medical interpreter sign the consent form (either in-person, electronically, or by documenting the use of an interpreter in the medical record)?</li> </ul>	Yes No
6)	As part of the informed consent discussion, do clinicians at your facility use the "teach back method" with patients/legal guardians, where patients/legal guardians are asked to describe, in their own words, what they understand will be performed, why it will be performed, and what are the primary risks?	Yes No

### Section 3D: Informed Consent – New and Updated FAQs for 2024

Should we consider the term "legal guardian" to be equivalent to the term "legal surrogate decision-marker"? Yes, for the purposes of the Leapfrog ASC Survey, these terms are identical.

# Regarding the process for soliciting patient feedback in question #2, what parameters should this process follow? Is there a specific patient feedback evaluation form that should be used?

Any method of soliciting feedback from patients who have gone through your informed consent process would be acceptable. Asking about the specific verbiage used in the consent form, as well as more general questions about the consent process itself, would both be acceptable areas of inquiry. It is Leapfrog's goal to encourage surgery centers to ensure their process is working well for patients by being as flexible as possible in allowing for differing methods.

For an example of a survey of patient's experience with the informed consent process, see: Hallock JL, Rios R, Handa VL. Patient satisfaction and informed consent for surgery. Am J Obstet Gynecol. 2017 Aug;217(2):181.e1-181.e7. doi: 10.1016/j.ajog.2017.03.020. Epub 2017 Mar 28. PMID: 28363439.



# Does the consent form need to specifically name the assistants and trainees who will be involved in the procedure, the same way the consent form needs to name the clinician performing the procedure?

No. The consent form only needs to indicate that assistants or trainees may be involved, if this applies to the specific procedure the patient is signing the consent form for.

# Why has Leapfrog selected a 6th-grade reading level target for consent forms, and what are some strategies we can use to meet this?

Just over half of U.S. adults have a reading level that permits them to understand and synthesize information from a complex text. According to a Gallup analysis, 54% of Americans between the ages of 16 and 74 read below the equivalent of a sixth-grade level. A more recent survey by the Organization for Economic Development and Cooperation (OECD) indicates that literacy in the U.S. has gradually declined since that Gallup analysis, suggesting a still-greater proportion of the population reads below a sixth-grade level today. Leapfrog has included an exemption in the standard for the procedure name and description, which may include highly technical language that would affect the reading level.

Leapfrog hosted two Town Hall Calls last year led by AHRQ describing techniques for reducing the written complexity of consent forms. The slides are available on Leapfrog's Town Hall Calls webpage; please refer to slide 40-47 for more information on the "Informed Consent" slide deck and slides 40-45 in the "Health Literacy" deck. Additional resources include:

- AHRQ Training Module
- The Patient Education Materials Assessment Tool (PEMAT)
- Clear Communication Index (CCI)
- CMS Toolkit for Making Written Material Clear and Effective

### How should the reading level of the consent form be assessed?

There are software tools available to assess reading level. For example, consent forms can be edited in Microsoft Word 365, where a readability tool can be used to make this assessment by: (1) on the "File" tab, click the "Options" button; (2) on the "Proofing" tab, under "When correcting spelling and grammar in Word", select the "Show readability statistics" check box. Exit the window. Then, under the Review tab in your Word document, click the "Editor" button in the far-left corner of the ribbon, then click "Insights – Document Stats" on the "Editor" sidebar: Word displays a message box showing you the Flesch-Kincaid readability grade-level: any value less than or equal to 6.9 is considered a "sixth grade" reading level. Reading level can also be assessed using online tools, such as those provided at Readable.com, provided those tools use either the Flesch-Kincaid or SMOG readability standard to evaluate the readability of written language.

### What information on the consent form can be excluded from the reading level assessment?

The procedure name and description can be excluded from the reading level assessment. In addition, information intended to be read by the provider or administrative staff ONLY, such as instructions for signing and returning the consent form, and information that is written in by an individual provider to give that patient information specific to their condition, can also be excluded. Finally, any words where a sixth-grade reading level definition is included with the term can be excluded from the reading level assessment. For example, in the sentence "anesthesia (putting you to sleep)", only "putting you to sleep"



needs to be considered in the reading level assessment.

### What is a qualified medical interpreter?

In the <u>U.S. Department of Health and Human Services 2023 Language Access Plan</u>, a qualified medical interpreter is defined as "A bilingual/multilingual person who has the appropriate training and experience or demonstrated ability to fully understand, analyze, and process and then faithfully render a spoken, written, or signed message in one language into a second language and who abides by a code of professional practice and ethics." Leapfrog adheres to that definition for the purposes of reporting on the ASC Survey.

### Section 3D: Informed Consent – Scoring Algorithm for 2024

Informed Consent Score (Performance Category)	Meaning that	
Achieved the Standard	<ul> <li>The facility responded "yes, <u>all</u> applicable forms are written at a 6th grade reading level or lower" to question #5, <u>and</u></li> <li>The facility responded "yes" to the remaining <u>five</u> questions in         <ul> <li>Policies and Training (question #1),</li> <li>Content of Informed Consent Forms (questions #3-4), and</li> <li>Process for Gaining Informed Consent (questions #6-7).</li> </ul> </li> </ul>	
Considerable Achievement	<ul> <li>The facility responded "yes, <u>all</u> applicable forms are written at a 6th grade reading level or lower" to question #5 <u>and</u></li> <li>The facility responded "yes" to at least <u>four</u> additional questions in         <ul> <li>Policies and Training (question #1),</li> <li>Content of Informed Consent Forms (questions #3-4), and</li> <li>Process for Gaining Informed Consent (questions #6-7).</li> </ul> </li> <li>OR         <ul> <li>The facility responded that "no, but at least <u>one</u> form is written at a 6th grade reading level or lower" <u>OR</u> "no, all applicable forms are written at a 9<sup>th</sup> grade reading level or lower" to question #5 <u>and</u></li> <li>The facility responded "yes" to the <u>five</u> remaining questions in             <ul> <li>Policies and Training (question #1),</li> <li>Content of Informed Consent Forms (questions in 9<sup>th</sup> grade reading level or lower" to question #5 <u>and</u></li> <li>The facility responded "yes" to the <u>five</u> remaining questions in                  <ul></ul></li></ul></li></ul></li></ul>	
Some Achievement	<ul> <li>The facility responded "yes, <u>all</u> applicable forms are written at a 6th grade reading level or lower" <u>OR</u> "no, but at least <u>one</u> form is written at a 6th grade reading level or lower" <u>OR</u> "no, all applicable forms are written at a 9<sup>th</sup> grade reading level or lower" to question #5 <u>and</u></li> <li>The facility responded "yes" to at least <u>three</u> additional questions in <ul> <li>Policies and Training (question #1),</li> <li>Content of Informed Consent Forms (questions #3-4), and</li> <li>Process for Gaining Informed Consent (questions #6-7).</li> </ul> </li> <li>OR <ul> <li>The facility responded "no forms are written at a 6th grade reading level or lower" to question at a 6th grade reading level or lower and the facility responded "no forms are written at a 6th grade reading level or lower" to questions at a 9th grade the facility responded "no forms are written at a 6th grade reading level or lower" to question #5 <u>and</u></li> </ul> </li> </ul>	



	<ul> <li>Policies and Training (question #1),</li> <li>Content of Informed Consent Forms (questions #3-4), and</li> <li>Process for Gaining Informed Consent (questions #6-7).</li> </ul>	
Limited Achievement	The facility responded to all the questions in this section, but it does not yet meet the criteria for Some Achievement.	
Limited Achievement	The facility responded to all the questions in this section, but it does not yet meet the criteria for Some Achievement.	



## \*END OF DOCUMENT\*