



AADE
American Association
of Diabetes Educators
ADVOCACY

**AADE ANALYSIS ON DRAFT GUIDANCE FOR
BLOOD GLUCOSE MONITORING SYSTEMS**

November 2014

AADE

200 W. Madison Street, Suite 800

Chicago, IL 60606

SUMMARY

The American Association of Diabetes Educators (AADE) was commissioned to conduct an analysis of the recent comments and feedback provided to the FDA on draft guidance for blood glucose monitoring systems. “Draft Guidance for Industry and FDA Staff – Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use and Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.”

Taking into consideration that open comment data can easily be skewed by virtue of a high usage of standardized ‘form’ or ‘cut and paste’ letters AADE conducted an in-depth analysis of the 578 comments received in order to gain an accurate representation of the true feedback provided to the FDA on these issues. AADE also analyzed the degree to which the public comments represented broad diversity of thoughtful opinion, or were the result of form letter requests – typically sent to by an organization to its members to encourage “easy action” on an issue.

**ISSUES INVOLVED IN ANALYZING THE COMMENTS ON POINT-OF-CARE (POC) AND SELF-MONITORING
BLOOD GLUCOSE TEST SYSTEMS (SMBG) GUIDANCE**

While the report is intended to provide an accurate snapshot of the positions taken by both consumers and various non-profit associations and public corporations on these issues, as well as a more granular analysis of the themes covered, there are several key points to keep in mind when reviewing the material. One important consideration is that this type of analysis has a number of subjective aspects, such that a cumulative tabulation is virtually impossible to achieve to a 100% mathematical certainty. These subjective aspects, including discussions on these matters with FDA staff, are noted below.

While the positions taken by the majority of comments are obvious, there are some where the writer's 'ask' was somewhat ambiguous, or they took the opportunity to expound on an issue that appears outside the scope of either the Point-Of-Care (POC) or Self-Monitoring Blood Glucose Test Systems (SMBG) issues we were asked to address, or offered apparently benign technical clarification suggestions.

Another issue we encountered in the review was a number of instances where an individual would candidly admit they submitted more than one comment ("I forgot to mention X") or ("I also want to point out Y"). In other cases, we noticed a marked similarity of names among consumer responses, such that the likelihood of different people having the same name in this relatively small public pool would appear to be unlikely. There are also a large number of form-letter 'anonymous' consumer comments.

In developing an appropriate tally of comments, we also found an instance where a group of physicians submitted a letter, which would then be resubmitted by one or more of the practice's physicians and so appear as a new comment in the FDA-generated list of comments. We noticed another comment letter was submitted by several national health professional associations, raising the question as to whether that particular submission should be considered as one public comment or separate comments by the named associations.

The majority of POC comments by academia appear to have been generated from CA-based university facilities. A few individuals also submitted comments that are self-styled as 'working in academia' or as a 'professor'.

Also, some commenters could conceivably have more than one designation: e.g. some writers self-identified as both a provider and a consumer, and they may or may not name either their particular scope of practice or their facility. Some groups, e.g. JDRF, could reasonably be considered as either a health association or a patient group. We decided to designate them as a patient group. We know that some of the individual consumer responses were from individuals who represent large patient coalitions; however, as these individuals submitted their comments based on their own experience and not under the guise of their patient-based organization, we designated them as individual consumers. Some providers submitted comments apparently on behalf of their facility, but others were unclear, so we put those comments into the health provider category.

Last, some anonymous writers appeared to be from either the device or other health care industry, yet submitted their material as ‘consumers’ using the standardized form letter that was most common through almost all of the individual consumer comments.

FDA VIEWS

To assist us in organizing the data, we discussed the comments with FDA staff in charge of analyzing the material. We have learned that many of the issues noted above have been the subject of internal staff discussion and review and still may change prior to the issuance of final guidance, but some parameters appear to have been agreed upon. FDA staff has decided that comments submitted by all individuals will be considered by the FDA as separate comments. One person may have submitted several comments, but that may not always be possible for the FDA to verify. Each anonymous letter is also considered as a separate comment. However, multiple different submissions by someone who acknowledges that they are providing follow-up comments are considered as one comment letter, addressing multiple issues.

Health provider letters signed by more than one provider are also considered as one comment by the FDA; however, if the health professionals in question also submitted the same letter again in a separate issuance, then the FDA would count that as a new (i.e. 2nd) comment. However, the multi-signature letter signed by 3 health associations would only be considered as one comment.

When we queried the FDA as to the logic behind this seemingly conflicting reasoning, particularly in the case of the multi-signed health professional letter and the multi-signed professional association letter, we were told that this has been a matter of internal discussion but the decision was reached that those

providers who chose to resign and send it in a second (or third time) should be considered as a ‘new’ comment.

However, the FDA believes that large health/trade associations who may comment on behalf of all their members would generally only be considered as one letter, unless various members also took the time to copy and send the same letter. This applies to a letter signed by several national associations. We understand the rationale behind a trade/professional association serving as ‘one’ comment on behalf of the named organization, but we believe a fairer representation of the views of large national health associations in cases where a letter is signed by 3 different associations should reasonably be considered as 3 comments, not one. For this reason, we have chosen to consider that letter as representative of the views of each separate national health association and so have counted them separately.

We noticed at least one hospital/health system resubmitted the same letter with the same signer several times, and so only counted that as one comment.

FDA staff tells us that internal review of this project is already resulting in significant revisions to the draft guidance, and that it will be some months before a final product is expected. They also indicate that, regardless of the high incidence of so-called ‘form’ letter consumer responses, they do not consider that to be a detriment, but instead recognize that many patients/consumers/family members are more comfortable discussing a highly technical issue using a prescribed form letter. They pointed out that many consumer form letters contained personal stories or other relevant information which is intended to convey the importance of their own individual situation. Thus, despite the fact that the basic letter utilized by most consumers is clearly a form letter, the FDA considers it an indication of the amount of

public interest afforded to this issue, as well as the fact that some individuals took extra time to convey their particular story. We do not know, however, how the FDA will balance these several hundred letters in the context of the 29 million individuals (9.3% of the United States) who have been diagnosed with diabetes.

As the comments were still under assessment and review when this report was prepared, please note that FDA indicated that spread sheet preparation and overall analysis of how to consider some of the varied materials was still a work in progress.

With this as a background, and recognizing that different interpretations of the data could result in slightly different figures, we believe this report provides an accurate assessment of the issues raised. Because of the subjective nature of interpreting the comments in general, these numbers will in all likelihood not correspond precisely to FDA determinations.

OVERVIEW OF POC AND SMBG DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF

The following guidelines were used in tabulating the positions:

“Negative” comments were those in which the writer specifically asks the FDA not to issue the guidance and/or not issue without major revision.

“Positive” comments may include suggestions for improvement or stronger additions to the POC/SMBG Guidance, but were generally complimentary of the FDA, and approved of the steps taken.

“Neutral” comments may contain general statements about the importance of e.g. the need to ensure quality patient care, the importance of cleaning and disinfection, and the importance of safety, technical clarifications, or a focus on an issue outside the scope of the document in question (e.g. remember reimbursement”).

For the most part, we tend to think the majority of neutral comments lean on the side of “positive” but in many cases it would be impossible to read that into the specifics of these particular comments.

Commenters were grouped according to the basic type of organization/national interest/personal interest that each represented. As noted above, some commenters could fall into more than one category. The basic group headings of the commenters are listed vertically on the left side of the charts. Most headings are self-explanatory, with additional clarification on select items below:

- Government: a commenter writing on behalf of a named government unit. Note that Members of Congress have also contacted the FDA, but these comments are not included as part of the official public comment file. We understand that they will be considered as interested stakeholders, but precisely how this will be determined is unknown.
- Provider: physicians, allied providers, or a self-described ‘provider of care.’
- Hospital: some may identify as a ‘medical center’, ‘health center’.
- Hospital Association: major national associations representing hospital interests.
- Legal: law firm commenting on behalf of an unnamed client.
- Manufacturer: medical technology and related companies producing diabetes related products, supplies, or other products that support diabetes care.
- Patient Groups: diabetes organizations focusing on patient needs (note: JDRF included here).

- Professional Association: national groups representing specific healthcare providers, or diabetes diagnostic related services.
- Trade Association: industry trade groups representing common defined interests.
- Academia: usually university based facilities and/or commenter self-designating as working in academia.
- Individual Consumer: commonly a diabetes patient or relative.

The issues highlighted within the specific comments are listed horizontally:

- Accuracy Standards: consumer support of higher standards and interest that meters not meeting standards should not be considered Durable Medical Equipment (DME); professional technical concerns that standards were unachievable or that there was no clinical justification for same; and other technical comments or request for clarification on samples, testing, better labeling.
- Substandard Products: general comments to remove flawed products from the marketplace through better post-market surveillance; consumer letters detailing inaccurate meter readings, or mentions of flawed strip-meter scenarios.
- Worsening Patient Care: commonly focused on change of POC tests to ‘moderate complexity’ use and the impact the change would have on patient outcomes and delays in providing swift testing and bedside care, and the importance of blood glucose testing. Impact on specific patient populations was also noted.
- Innovation: Commonly focused on the impact CLIA waiver change would have on development of new products.

- ISO/POC: Almost always expressed concerns relative to the proposed need to change the current standards, or other conflicts with existing standards.
- Cost: Most concerns relative to the financial impact involved in adopting the reclassification change and impact on hospital scarce resources; some comments expressed general concerns about ‘cost’ and ‘reimbursement’ without a real frame of reference.

Following are the summary charts:

SMBG	Positive	Negative	Neutral	Accuracy Standards	Substandard Products	Worsening Patient Care	Innovation	ISO/POC	Cost
Provider	2			2					
Manufacturer		3	2	4	1	1	2		1
Patient Group	1	1		2	2	1	1	1	
Professional Association	2			1	2	1	2	2	1
Trade Association		2		2		2	2	2	2
Individual Consumer	341	26	2	103	97	9	2		
Total	346	32	4	114	102	14	9	5	4

POC	Positive	Negative	Neutral	Accuracy Standards	Substandard Products	Worsening Patient Care	Innovation	ISO/POC	Cost
Government		1	1	1					
Provider	4	20		9		15	2	3	10
Hospital		10		10		10			4
Hospital Association		3		2		3		1	
Legal		1		1			1	1	
Manufacturer		7	2	7	3		2		1
Patient Group		2		2		1	1		
Professional Association	1	7		2	1	5	2	3	1
Trade Association	1	2		3	3	3	2		1
Academia	1	9				10	2		6
Individual Consumer	108	4	2	103	97	9	2		
Total	115	66	5	140	104	56	14	8	23

PROFESSIONAL COMMENTS

Most healthcare providers, manufacturers, academia, and trade associations submitted negative comments focusing on the change of classification of POC tests from waived to moderate complexity. The concerns usually noted many problematic and disruptive results if the guidance was finalized: namely, that this change would not improve patient safety, as well as result in extensive extra resource allocation and expenses for facilities to implement such a change, including the required educational requirements of certain personnel. Estimated costs varied, with some exceeding \$100,000, as well as extra costs noted for proficiency testing, hiring of new nursing staff, and the like.

In addition to the extra costs, serious concerns about delays in care and the safety of patients were highlighted. Most commenters described how the current ‘waived’ category permits hospitals and providers to use these tests for timely, convenient assessment and to respond quickly when needed. A common criticism focused on a lack of any concrete evidence presented by the FDA evidencing a need for a regulatory change of this nature.

In essence, such a dramatic change will negatively impact the ability of hospitals and health providers to use blood glucose testing. Any diminution in the timely and efficient monitoring of patient blood glucose readings would ultimately lead to serious – and potentially life threatening – patient harm. Furthermore, many POC facilities have patient populations that need rapid assessments of their glucose levels and which are unequipped to provide alternative testing methods.

Many health professionals offered specific comments relative to limiting the use of blood glucose monitors for critically ill patients. Additional specificity was requested, as patients may be clinically

very ill but still may present no indications that would interfere with a blood glucose reading. There was concern that the guidance would cause confusion in hospitals as well as their regulating state and federal agencies.

Tangential to the issue of reclassification of certain POC tests, most professional associations expressed serious concerns with problematic or flawed devices currently on the market which could also cause patient harm that are being unaddressed by the FDA. These writers noted that the FDA is not using its existing regulatory authority to remove noncompliant products from the marketplace, but is instead proposing more stringent guidelines for future products. These commenters urged that the FDA enforce existing standards before raising the bar higher for future products.

By contrast, ACSLI, in referring to itself as the largest non-registry professional association for non-physician clinical laboratory professionals, supported the reclassification change, noting that POC devices must meet different standards, which would lead to better patient outcomes. There were no corroborating studies or evidence presented to support these comments.

It is worth reporting that one trade association based in the Northeastern U.S. was supportive of the POC Guidance. As their general position was at variance with the vast majority of other association or group-based submissions, we wanted to highlight this position. (*“GNYHA Ventures has long believed that guidance for the professional use point-of-care glucose meter is much needed and long overdue, both from accuracy and patient-safety perspectives. We are extremely pleased that the Administration has issued this much anticipated and important guidance, and urge timely adoption of its provisions.”*)

Some professional commenters noted a lack of discussion in the guidance of the differences that exist between reference methods. One writer noted that whether a system meets the criteria will depend on the reference method it is calibrated to and compared against. (Abbott and Roche were mentioned).

A few health professionals focused on the validation of POC meter readings of samples taken via capillary, venous and/or arterial routes, and questioned the methodology, e.g. if a sample from an indwelling catheter was contaminated, the meter would not be available as a safety net. A known limitation of arterial line sampling was noted, namely that if a sample is contaminated by the infusing IV fluid, then both the meter and lab values will appear to be validated. However, they will both, in fact, be in error. A capillary sample, with no such contamination would, in fact, be a more reliable reflection of the patient's actual condition.

Commenters noted that the question of multiple contributions by a single participant is not addressed in the Guidance. For successful recruitment and completion of the testing, this aspect was encouraged.

Also, commenters noted that, for ICU patient sampling, the question of venous confirmation of arterial sampling must be considered. The primary indication for an indwelling central arterial line is poor or no venous access, therefore, the requisite venous laboratory sample may not be able to be obtained. And given the risks of infection and potential of vessel damage, it was noted that arterial sampling must be confined to those patients with existing indwelling arterial lines or undergoing blood gas sampling for reasons other than study participation. This should be clearly stated to reinforce that performing arterial blood sampling solely for study purposes is not acceptable.

The need to adhere to existing ISO standards and promote product innovation was a common theme. Manufacturers and some professional associations were critical of the need to disregard current

ISO/POC guidance. The Guidance accuracy standards were variously described as unachievable, unnecessary, and/or clinically inappropriate. The FDA was strongly encouraged to delay issuance of any final Guidance until such time as these technical issues could be better addressed. This was also stressed in a letter from Congress signed by 85 members. This letter was not included in the official log of public comments as it was sent directly to FDA Commissioner, Margaret A Hamburg, M.D., but we understand that it will be given consideration as the Guidance documents are revised. Following is a link to the letter:

http://www.diabeteseducator.org/_resources/Advocacy/FDA_BGM_GUIDANCE_CONGRESSLETTER_2014.pdf

On the technical areas of the guidance, trade associations expressed concern about deviation from recognized standards such as EP07-2A for lab interference testing and this was supported in comments made by CLSI (Clinical and Laboratory Standards Institute).

Substantial comments were made on general labeling and terminology; e.g. manufacturers and consumers alike found the term ‘prescription use’ confusing. Home use should not be restricted to the home.

A small portion of health provider comments were strictly focused on technical issues surrounding cleaning and disinfection, while larger organizations tended to highlight those issues among others. As contrasted with concerns expressed on the POC Guidance, professional associations submitted fairly positive comments on the SMBG Guidance and noted the need for accuracy; however, organizations also focused on the need to protect patients from harmful devices that should be removed from the marketplace, as well as the need for layman-friendly labeling terminology.

One state government commenter asked several questions about hand hygiene and disinfection. Since that focus area does not appear to comport with issues of interest in this report, we simply noted that as a Neutral comment.

CONSUMER COMMENTS

For the most part, the individual patient/consumer/family member letters were highly duplicative and a variation of a few form letters was used for both the SMBG and POC Guidance. Some writers did take the time to expound on their own personal story, and a few cut and pasted select portions of the form letter without using it in its entirety. The duplicative consumer letters will be apparent to the FDA, but there are also clear signs of desperate appeals by these consumers to make meters safer, address the issue of strip-meter fallibility, and ensure accurate readings.

By and large, consumers not surprisingly, promote higher standards and believe that POC and OTC meters should have the same ‘high’ standards that are ‘economically feasible’. Some consumers focused exclusively on the fact that any deviation from POC to OTC standards was simply not good enough. These letters focused on the dangers of insulin, the need to make moment-to-moment decisions and how insulin administered at home should be as safe as that administered in a hospital. A few negative consumer comments appear to be from industry sources, based on the phrasing used.

58 consumer responses in the BGMS draft are anonymous. 36 consumer responses in the POC draft are anonymous. Some consumer BGMS focused exclusively on the high cost of strips, flawed strips, lack of reimbursement, and the need for better quality control of 3rd party strips.

The BCMS consumer-generated draft promoted: accuracy at the highest levels feasibly possible, the need for post market surveillance, a robust MDR (Medical Device Report) file, a need to ensure that only meters meeting the new higher standards will be eligible for reimbursement as DME, and a general need for new specific quality and labeling requirements to prevent 3rd party payors from limiting coverage to older meters and to prompt manufacturers to move expeditiously (i.e. prevent them from ‘dragging their heels’). A copy of the letter is at the bottom for ease of reference.

KEY TAKE AWAYS

Consumers and patient groups desire the highest meter standards possible and would prefer to see a uniform high standard. Many do not seem to understand the nuances involved and/or they perceive that their home meter is somehow less trustworthy. These perceptions appear to be based on highly negative experiences with flawed meters that are currently on the marketplace and which provide extreme fluctuations in blood glucose readings, which could be life threatening. Specific examples and personal stories were noted.

The sheer volume of positive consumer letters exceeds the volume of negative positions taken by most manufacturers, trade associations, hospital and health associations and academia. As noted earlier, the official FDA position is that these form letters are given relatively equal weight. But it seems clear that many of the form letters may have been resubmitted to help increase overall quantity, and in a few instances, it appeared that consumers had other family members send in the same letter.

By contrast, the professional letters expressing serious concerns with the POC and OTC guidance were, by and large, not following the same duplicative form script as those on the consumer side.

Primary points can be summarized as follows:

- The core problem with accuracy in blood glucose testing centers around those SMBGs that do not meet quality standards. The FDA is not addressing this issue and should do so before suggesting a new set of higher standards;
- There is no evidence supporting the FDA's decision to deviate from industry-accepted ISO/POCT standards;
- There is no clinical evidence or justification put forth by the FDA as to the reason for changes in the Guidance, many of which are technologically impossible for manufacturers to achieve; others will directly impact care; and increase costs for providers;
- Adoption of the Guidance in its current form will delay patient care in general, but will be especially problematic for certain patient populations. Hospitals may have to resort to lab testing for glucose monitoring.
- The FDA policy to accept multiple form letters as unique individual responses while considering a letter signed by several national health professional associations as one comment would give the appearance of a bias toward consumers. Perhaps to avoid the impression of bias, the FDA has indicated that, if other associations were to also file the same letter, then those letters are considered as 'new' comments by the other filing association(s). This information may be most useful in future comment submissions by national associations that customarily sign onto one letter, namely: each association should also submit the letter on behalf of its own respective members.

- Consumer letters were apparently generated from various sources, including an online article advocating for: tighter accuracy readings for POC meters which would eventually apply to all meters, a stronger statement by FDA that meters not meeting the new standards are not considered DME, a post market surveillance program, and new labeling requirements.
- In addition to the Diabetes Caucus congressional letter, we understand that other Members of Congress also sent letters of inquiry, some apparently raising various concerns, while others are relatively benign reflections on the need to ensure quality patient care. There is no ‘magic number’ of congressional letters that may help influence FDA’s decisions, but the Caucus letter clearly represents a respectable and noteworthy indication of congressional interest and concern regarding certain aspects of the Guidance. As with any agency issuance of this nature, the final Guidance should reflect sound scientific guidance, medical principles on best practices, and industry capabilities that are able to achieve the goals of quality diabetes patient care, which should be carefully considered before a final document is issued.
- An early FDA summary appears to group comments into two somewhat random categories: one primarily of individuals and health professionals, and a second group into ‘device industry and associations’. While the FDA may continue to refine the comments as time goes on, this early random summation does not appear to incorporate the breadth of various input into the Guidance process. Specifically, the comments appear to give greater implied weight to the “support” side for higher standards, while minimizing the approximate 100 comments from a variety of different provider, professional association, patient group, academia and trade groups, many of whom

expressed various concerns on issues ranging from the impact the current draft Guidance would have on patient care and safety, cost concerns, lack of justification for changing certain current guidelines, and the potential for placing an essential blanket restriction on the use of OTC BGMS in hospital or other professional healthcare settings. The FDA summary also does not appear to incorporate the scope of congressional interest expressed to the FDA Commissioner on this issue.

INDIVIDUAL CONSUMER FORM SAMPLE LETTER

We found many encouraging ideas in the FDA’s draft guidance. Its tighter accuracy standards (particularly in the hypoglycemic range) are a huge step forward. The new emphasis on test strip lot release criteria will hopefully lead to better quality control, and the proposed requirement for front-of-package accuracy information will make clear that the quality of blood glucose meters varies, and allow users to make informed choices.

SUGGESTIONS:

CLARITY

The terms “over-the-counter-use” and “prescription point-of-care” use are confusing. Instead, “for patient personal use” and “for professional in clinic use” would make the distinction clearer.

ACCURACY

Insulin is a very dangerous drug. Reports show insulin to be a leading cause of adverse drug reaction emergency room admissions.* Insulin is dosed based on meter readings. People with diabetes have a real need for accuracy in our lives, outside the hospital to preventing the adverse insulin reactions that

cause ER admissions. Both the patient self-use and the caregiver-in-office-use meters should have the same mandated level of accuracy. Dr. David Sacks of NIH suggests the proposed professional standards may not be possible at this time.# Accuracy should be required at the highest level that is economically feasible.

*drugs.com/news/adverse-reactions-new-national-perspective-risk-1954.html

#Close Concerns. 2014-2-27

POST-MARKET

Currently there is no program in place to review devices to ensure they continue to maintain the accuracy for which they were approved. This allows quality to slip over time, and puts patient health at risk. There should be a post-market surveillance program with the ability to remove unqualified meters from the market.

MEDICAL DEVICE REPORTS

There is a wide discrepancy between manufacturers in the number of Medical Device Reports (MDR) that they file.* This is problematic since, as the FDA has stressed, MDRs are essential for the post-market evaluation of glucose meters; failure to comply with MDR requirements puts patient lives at risk. This guidance should require criteria for robust MDR policies, similar to the proposed lot release criteria, in order for a meter to be cleared.

* Close Concerns. 2013-5-27

DOSE INSULIN

The FDA stated in a December 2013 clearance document that “Blood Glucose Meter Accuracy is the most important criteria in determining glucose meter quality.” It also indicated in that document that the 2003 accuracy standards (which this guidance would replace) may not be sufficient, because it required the meter in question — which met the 2003 requirements — to be sold with the following all-cap warning: “DO NOT USE [the meter] TO CALCULATE INSULIN DOSES. DO NOT USE [it] TO CALIBRATE CONTINUOUS GLUCOSE MONITORS.”* The new guidance should make clear that only devices which meet the tighter standards can be cleared by FDA to dose insulin or calibrate continuous monitors (and thus be considered DME).

DURABLE MEDICAL EQUIPMENT

The FDA must also be clear that meters that do not meet the new accuracy requirements should not be considered “durable medical equipment.”

The guidance should explicitly state that the only blood glucose meters that can be considered “durable medical equipment” by payers are those that the FDA determines can be used to “make therapy adjustments” — meaning that they’re accurate enough to calculate insulin doses or to calibrate a CGM. Any meter that does not meet the necessary level of quality (and maintain it post-market) cannot be considered DME, and therefore should not be considered eligible for Medicare/health or private insurance reimbursement as DME for diabetes. (The quoted language comes directly from CMS.)

THERAPY ADJUSTMENTS

The proposed labeling requirements should specifically state whether a meter has received FDA clearance to “make therapy adjustments” — a statement that could only be made if the meter and its strips met, and continued to meet, these proposed new accuracy standards. Again, this phrasing would clearly distinguish which meters should be eligible for insurance coverage, since only those that are accurate enough to be used for therapy adjustments should qualify.

CONCLUSION:

The proposed new standards are a positive step, but they can only be effective if they are accompanied by specific quality and labeling requirements that prevent third-party payers from limiting coverage to antiquated meters, and meter/test strip manufacturers from dragging their heels. These proposed changes, when combined with a post-market surveillance system and enforcement policy, will help ensure that I and all people with diabetes are able to safely manage our disease