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Advanced Medical Technology Association

**Blood Glucose Monitoring Technologies:
*Industry Perspective on Policy Challenges and
Assuring Future Advances and Innovation***

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- Introduction
- Objectives
- Proposed Changes to BGM Regulation—
Implications & Solutions
- Competitive Bidding Program—Concerns for
Diabetes Testing Supplies & Solutions
- Next Steps

BGM test systems and continuous glucose sensing are the cornerstone of effective diabetes management.

Commitment to designing and manufacturing meters that meet the needs of individuals with diabetes

- Reduce use error
- Reduce the impact of interferents
- Improve meter accuracy

Goal: Improve overall quality of testing for patients

Non-clinically grounded, non-harmonized regulatory standards prevent entry of high quality innovative products.

Reimbursement models that favor cost versus quality are a disincentive for innovation and can harm patient access.

Draft OTC and Prescription POC Guidances

- FDA proposed 2 guidances (Jan 2014) that:
 - Resulted in extensive comments on proposed details of these proposals.
 - Proposed significant change to BGM regulation.
 - Potential negative impact on BGM access to healthcare professionals & consumers.
 - Proposed blanket restrictions on use of POC technologies for healthcare professionals via labeling.
- **Solution**
 - Carefully consider overall implications.
 - Provide better harmonization with worldwide improvements through latest standards and guidelines for OTC and hospital-use.
 - Ensure all changes are evidence-based, clinically grounded, well defined, feasible, and risk-based.
 - Convene public workshop prior to issuance of final guidances with HCPs, industry, and others stakeholders to discuss scientific/technical issues.

Any New Policies Must Support Access and Innovation

While well intentioned, any final guidances must guard against unintended consequences for healthcare professionals and patients.

- Not impose new blanket labeling restriction on all HCP use of OTC meters.
- Differentiate tight glycemic control from other HCP use (not any and all uses).
- Recognize that HCPs are as proficient as patients, if not more, at performing testing.
- Consider implications (extensive stakeholder comments re. access to new/improved devices, less user friendly, higher cost)

Any final guidances must better support harmonization with worldwide standards and guidelines [ISO 15197: 2013 and POCT-12 (A3)].

- Better harmonize with stringent internationally recognized standards available and implemented worldwide (ISO 15197 for OTC & POCT-12 aimed at hospital TGC and others e.g., EP7-A2.).

Ensure any changes in final guidances are evidence-based, clinically grounded, well-defined, feasible, and risk-based.

- Assess any changes in larger clinical context/impact on clinical outcomes.
- Convene public workshop to discuss scientific/technical issues before final guidances.
- Distinguish pre/postmarket. FDA should enforce adherence to postmarket quality system regulation through inspection, MDR review, recall, & other robust authorities for any substandard products.

Blood Glucose Meters are considered **Durable Medical Equipment (DME)**

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is used primarily and customarily to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and
- Is appropriate for use in the home.

Diabetes test strips are **Supplies** necessary for the effective use of DME

Medicare spends about \$8 billion on all covered DMEPOS items

- In recent past, diabetes testing supplies amounted to about 18% of total spending for DMEPOS

DMEPOS Competitive Bidding Program

In 2003, Congress required the Secretary to establish a “competitive acquisition” program for DMEPOS

- Government reports (OIG, GAO) finding Medicare payment rates higher than prices charged for identical items furnished to non-Medicare customers.
- Fraud and abuse

Congress required **phase-in of program**

- **By area of the country, and**
- **By highest cost and highest volume items or items that have the largest savings potential**

To date, 3 rounds of bidding and a National Mail Order Program for diabetes test strips—3-year contracts for winning bidders.

Current National Mail Order Program contracts for DTS expire June 30, 2016. Bidding for new contracts for the National Mail Order Program Recompete will begin Winter 2015.

Mail order companies—”suppliers” in Medicare nomenclature—must meet certain accreditation standards:

Financial management, contact information, after-hours access, emergency contact, training/instruction for beneficiaries

Product requirements—can not be adulterated, counterfeit, misbranded, and not obtained by fraud and abuse



National Mail Order Program for DTS reduced average price by 72%, as compared to amounts Medicare had been paying

American Taxpayer Relief Act enacted January 2, 2013, P.L. 112-240, requires that payment for retail pharmacy DTS be equal to the single payment amounts established under the National Mail Order Program

CMS deems program a success

- \$25.7 billion in savings to Medicare over 10 years
- An additional \$17.1 billion/10 years in savings to beneficiaries in terms of reduced cost sharing and lower Part B premiums
- 42% reduction in spending due to:
 - lower prices for items
 - reduced utilization
- Very few beneficiary complaints
- Less fraud and abuse

Real-time claims monitoring

- CMS has found no detectable differences in rates of mortality, hospitalization, emergency room visits, physician office visits, SNF admissions between competitive bidding areas and comparator MSAs

Binding Bids

- Bids in competition are not binding: encourages low-ball bids that can impact quality of items available to beneficiaries.

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- Will low single payment amounts determined through competitive bidding ensure that beneficiaries will have access in the future to innovations that will improve health, e.g., CGM.

Evaluation of Impact

- CMS has not undertaken in-depth evaluation of impact of program on beneficiary health. Letter to OIG from 138 Members of Congress calling for multi-pronged evaluation of program.
- Recompete for National Mail Order Program should be delayed until impact is understood

AdvaMed Concerns with DTS in Competitive Bidding—50% Rule

50% Rule

- Medicare law requires that CMS award contracts for mail order diabetic testing strips to suppliers who provide at least 50%, by volume, of all types of mail order strips previously available to beneficiaries
- CMS enforces only at the time it awards a contract—not during the 3-year contract period
- Supply Chain for testing strips/meters has changed
 - None of the 7 companies accounting for 50% of the market in 2009 are among the 4 companies accounting for 50% of market in 2013
- January 2014 American Association of Diabetes Educators' (AADE) survey of national mail order suppliers found that:
 - Only 3 suppliers carried each brand of DTS they reported as carrying to Medicare
- **Solution**
 - Require that the 50% rule be a contract term, enforced during 3-year period
 - Require suppliers to demonstrate that they will be able to purchase sufficient quantities of test strips the supplier says it will make available
 - Evaluate patient well-being

Anti-Switching Rule

- CMS initiated a regulation that:
 - requires suppliers to furnish the brand of test strips that work with the monitor currently in use by the beneficiaries
 - prohibits suppliers from inducing or incentivizing beneficiaries to switch testing systems
 - prohibits the supplier from furnishing information about alternative systems unless asked
- Medicare beneficiaries report being sent unsolicited, new monitors
- **Solution**
 - Require suppliers first to request a prescription from beneficiary's physician before changing testing systems
 - Require suppliers to inform patients that they are able to keep their existing systems, that suppliers are required to furnish patient's current brand of test strips, and that they have the right to return products
 - More aggressive monitoring by CMS of violations of regulation requirements

Medicare Payments for DTS in Retail Pharmacies

- 2013 law requires CMS to pay retail pharmacies the same amount for test strips as determined through bidding under the National Mail Order Program
- CMS had proposed recognizing the different business model of pharmacies through differential payments for each setting
 - A differential payment would create a safety net for Medicare beneficiaries to obtain testing systems their physicians believe are appropriate for them
 - Also would create a disincentive for mail order suppliers to try to change beneficiary testing systems
- Challenge
 - To recognize a differential would entail a cost to Medicare that would have to be offset with savings from another provision



Insulin pumps included in a round of competitive bidding known as the Round 1 Re compete.

For purposes of bidding, insulin pumps included in a larger product category with Infusion Pumps. Bidders wanting to become a contract supplier had to submit bids for both products, even though the technologies and particular patient issues might be very different.

Reports of compromised patient access to insulin pumps, perhaps because winning bidders unfamiliar with the technology.



In general, we are finding that Medicare's coverage and reimbursement for medical technology is becoming increasingly difficult. Documented by Tufts Institute for Clinical Research and Health Policy Studies.

Private plans cover glucose sensing/CGM technology, but Medicare does not. Medicare does not cover, even though studies show that:

- using sensing/CGM technologies can significantly improve diabetes control and decrease frequency of high and low blood glucose
- regular use can result in better diabetes control.

Challenge:

- CMS must either change its mind or Congress will have to act to mandate coverage.
- S. 2689 and H.R. 5644 recently introduced to mandate coverage of CGM for medically appropriate patients with diabetes.



JDRF funded 10 site, independent trial to test effectiveness of CGM use by those with T1

- Randomized those with T1D into CGM+SMBG and SMBG alone
- Results published in NEJM and Diabetes Care: adults using CGM+SMBG vs SMBG alone
 - Improved glucose control (reduced A1c)
 - Reduced rate of severe hypoglycemia²

AHRQ Comparative Effectiveness Review ¹

- Rt-CGM is superior to SMBG in lowering A1C without added risk of hypoglycemia.
- Sensor-augmented pumps are superior to MDI/SMBG in lowering HbA1c

AHRQ Medicare Use of Diabetes Care

7 million Medicare FFS beneficiaries have diabetes.

Those with type 1 diabetes or with type 2 diabetes who use insulin have disproportionately high hospitalization, emergency room use, and mortality

¹ A1c of CGM group was .5 lower than control group. JDRF CGM Study Group, N Engl J Med 2008 359:1464–1476

² CGM group had rate of 7.1 events per 100 person years vs. 21.8 for control group. JDRF CGM Study Group, Diabetes Care 32:2047–2049, 2009

Adopt policies that promote innovation and access to critical blood glucose technologies.

Ensure consistent FDA/CMS policies for providing patients access to quality blood glucose technologies.