PharmaSmart applauds AHA/AMA initiative creating valid blood pressure device list

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ROCHESTER N.Y. — PharmaSmart International Inc., a leading health screening, and digital health management company, praised the American Heart Association (AHA) and American Medical Association (AMA) for their joint initiative to create the country's first validated blood pressure (BP) device listing. The company welcomed the announcement, which will ensure that physicians, pharmacists, and patients have a single, trustworthy reference for identifying clinical-grade blood pressure devices.

In a statement published in the "AMA Wire", the AMA referenced the new 2017 national hypertension guideline that states all BP monitors used for self-measurement should be backed by peer-reviewed, independent clinical validations. In order to be in compliance with these professional guidelines, the AMA stated that patients and physicians need a "comprehensive, unbiased resource" to use when selecting a valid BP device for self-measurement.

The AMA and AHA have released the draft criteria for devices to be included in the new listing. The criteria document makes it clear that the FDA status of a device does not substantiate device accuracy, stating, "substantial equivalence, as defined by the FDA and used for 510(k) device clearance, is not sufficient to meet the criteria for clinical accuracy." Per the draft criteria, in order for devices to be included in the list, the manufacturer must substantiate their claims with quality, independent evidence, using an acceptable international testing protocol.

A blood pressure expert quoted in the AMA Wire article noted that not all devices for sale have been validated, that "truth in advertising is always an issue," and that the current state of the device market is "buyer beware." The new AMA and AHA device list will cut through the noise, and provide physicians, pharmacists and patients access to a list of devices that have been clinically validated for accuracy.

PharmaSmart chief strategy officer, Josh Sarkis stated, "With the growth of Health IT and self-measurement of biometrics, we are seeing intense interest from national physician groups in blood pressure measurement accuracy." Sarkis continued, "We are advising our retail pharmacy clients to begin their compliance planning now. FDA clearance is no longer enough. Ask your BP device vendors if they can demonstrate, and guarantee, that their devices meet

the AHA/AMA criteria. Taking active measures now will insulate your brand reputation with the public, healthcare providers, and with payers, and will bolster your standing to deliver quality clinical care.”