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General Counsel

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SUBMITTED VIA WWW.REGULATIONS.GOV

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013.

**Re: File Code CMS-5060-P; RIN 0938-AR33; Medicare, Medicaid,
Children's Health Insurance Programs; Transparency Reports and
Reporting of Physician Ownership or Investment Interests**

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to File Code CMS-5060-P; Transparency Reports and Reporting of Physician Ownership or Investment Interests. AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, biological products and feed additives used in modern food production, and the medicines that keep livestock and pets healthy. AHI member companies represent the vast majority of the US market for animal health products.

It is clear from both the statutory language in section 6002 of the Affordable Care Act and the language used in the proposed rules in this docket that the transparency reporting contemplated focuses on transparency in payments related to human healthcare and does not contemplate veterinary medicine. The collection of information relative to veterinary healthcare would not further the stated goals for improving human healthcare. In order to facilitate the drawing of bright lines for compliance purposes, we request an explicit statement of exclusion when the rules are finalized.

The Act defines a "covered recipient" as a physician or teaching hospital. The definition of a physician under proposed 42 CFR § 403.902 encompasses doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors. It does not include doctors of veterinary medicine. A teaching hospital under proposed 42 CFR § 403.902 is an institution that receives payments under sections 1886(d)(5)(B), 1886(h), or 1886(s) of the Act. Veterinary teaching hospitals (i.e. those affiliated with veterinary medical colleges or residency training) do not receive such funds. As defined in both the Act and the proposed rules a "covered drug, device, biological or medical supply" does not contemplate products utilized in veterinary medicine. Payment is not available under the listed programs for the delivery of veterinary healthcare.

Despite this clear exclusion of veterinary medicine and the complete lack of contemplation of veterinary medicine by the Act or proposed regulations, we believe it would be beneficial to specifically exclude veterinary medical professionals, veterinary teaching

hospitals and products sold relative to veterinary medicine to prevent confusion. Confusion could arise because (1) companies that sell veterinary products may be affiliated with companies that otherwise meet the definition of an “applicable manufacturer” through the sale of covered products for use in the delivery of human healthcare; (2) veterinary teaching hospitals may be affiliated with university systems that also include hospitals that meet the definition of a teaching hospital for the delivery of human healthcare; and (3) veterinarians routinely use products approved for human use in an off-label (called extra-label by FDA) manner in the delivery of veterinary healthcare, and these may include products otherwise available for reimbursement under the listed programs for covered products when used by physicians in the delivery of human healthcare.

There is also concern by some that the proposed definition of a teaching hospital could be read to include veterinary teaching hospitals that are located on the same university campus as a teaching hospital that delivers human healthcare. As such, the veterinary teaching hospital could have some common identifying information, such as a similar campus address or other similarities by virtue of being part of the same university system. If veterinary teaching hospitals were included under such circumstances, the reporting would be incomplete as those manufacturers who did not otherwise meet the definition of an applicable manufacturer by virtue of selling covered products would not have triggered a reporting requirement. While we believe the correct interpretation of the proposed language would not require the reporting of information relative to veterinary medicine or veterinary teaching hospitals, a specific exclusionary statement will allow all manufacturers to exclude veterinary medicine confidently.

Additionally, were manufacturers to collect and submit information relative to veterinary medicine, it would place an unnecessary and unintended burden upon CMS to handle and exclude data that is inapplicable to the stated goals.

It is clear that veterinary medicine was not considered when the statute and proposed rules were drafted, therefore we request that CMS (1) confirm the exclusion of veterinarians from the definition of covered recipients, (2) confirm the exclusion of veterinary teaching hospitals from the definition of covered recipients, even if they are affiliated with the same university systems, and have common addresses or other similarities to covered teaching hospitals for the delivery of human healthcare, and (3) confirm that the reporting requirements do not attach to activity related to covered drugs, devices, biologicals or medical supplies when utilized in the delivery of veterinary medicine.

Sincerely,

Kent D. McClure