Week Six Business Law Assignment

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## Abstract

This essay provides an analysis of part of the rulemaking process in the government of the U.S. It begins by providing an insight into the federal register and the Code of Federal Regulation as well as providing the distinction between the two. It goes further by analysis the role played by each in the decision-making process. The second part covers the importance of the public comment period. The final part provides an analysis of the ethical issues surrounding the regulations for the interpretation of statutes on gifts offered to physicians. The government rules, notices, executive orders and presidential documents are published officially in the Federal Register. The Federal Register contains the Executive Orders, Federal Agency Regulations, Proposed Rules, proclamations, public notices and other presidential documents. The Code of Federal Regulations, on the other hand, is the collation of rules that have been published in the federal register by the government, the executive departments and other agencies.

Federal Register refers to the daily publication by the office of the federal register under the National Archives and Records Administration (NARA). It contains the Executive Orders, Federal Agency Regulations, Proposed Rules, proclamations, public notices and other presidential documents. The office of the federal register at NARA is mandated with the preparation and publication of the federal register in collaboration with the Government printing office (GPO). The federal register is distributed by the GPO in the paper, World Wide Web, and microfiche (National Archives, 2017).

The federal register plays a critical role in the rulemaking process. It ensures that agencies do not take actions that exceed their constitutional or statutory authority. This is ensured by the requirement under the Administrative Procedure Act (APA) that ensures agencies follow an open public channel in their actions. Majorly, this includes the publication of a rulemaking authority statement in the federal register. This applies to all of the proposed rules as well as the final rules. Agencies are also required to publish the unified agenda in the federal register. The federal register also publishes petitions for Rulemaking and an Advanced Notice of Proposed Rulemaking. This clearly illustrates that the federal register plays an important role in the rulemaking process.

The Federal Register (FR) can be differentiated from the Code of Federal Regulation in that, while the Federal Register is the official publication of government rules, notices, executive orders and presidential documents, the Code of Federal Regulations is the collation of rules that are published in the federal register by the federal government, the executive departments, and other agencies. The CFR is categorized into 50 titles which represent categories subject to federal regulation. The CFR is updated yearly and gets issued quarterly. The Electronic version is also availed in the World Wide Web (National Archives, 2017).

The 60 day public comment period referred to as a Notice of Proposed Rule Making (NPRM) is a notice to the public by a government agency wishing to remove, add or change a regulation. This is done as part of the rulemaking process. It is meant to introduce the element of public participation to the process of rule making by taking comments from the public. This procedure is provided for under the Administrative Procedure Act. It was created by the Congress in order to force the agencies to listen and take into account the concerns of the people affected by the regulation.

The financial relationships between doctors and pharmaceutical companies have raised a number of ethical concerns. Organizations such as the American College of Physicians (ACP) forbids physicians from accepting gifts and other incentives from pharmaceutical industries. Their argument is based on ethical concerns that such gifts might cloud their professional judgment and compromise their ability to take care of patients. Gifts and other incentives have also been noted to create a conflict of interests involving undue influence. Such incentives are also used as a disguise of bribes from the pharmaceutical companies (Twomey & Jennings, 2013).

As a result of such gross misconduct in the field of medical practice, regulations have been formulated by the Health and Human Services department aimed at the interpretation of statutes on benefits such as gifts offered to doctors by pharmaceutical companies. This will help regulate physicians involved in professional misconduct hence ensuring proper patient care. It is hence vital that medical practitioners adhere to the practice policies and professional code of ethics (Schachter et al., 2010).

## References

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