Medical Practitioners (Amendment) Bill 2017

Memo for the Joint Oireachtas Committee on Health from Deputy Billy Kelleher December 1st 2017

Overview of Bill

The Medical Practitioners (Amendment) Bill 2017 if enacted will medical practitioners to declare any income or gift received from medical suppliers or pharmaceutical companies to the Medical Council in statutory declaration annually.

Section 1 of the bill provides definitions.

Section 2 of the bill amends Section 45 of the Medical Practitioners Act 2007 in three ways. Firstly it provides that a registered medical practitioner shall on an annual basis, give to the Medical Council a statutory declaration signed by him or her giving particulars of all declarable income and gifts received from any medical equipment suppliers, its servants or agents, and or any pharmaceutical companies, its servants or agents, within the previous 12 months not before the 31st day of January of each year. Secondly, it provides that the Medical Council shall maintain a register of gifts and declarable income declared by each registered medical practitioner which shall be published by the Council on an annual basis in electronic form in a publicly accessible and searchable manner. Finally, it provides that failure to comply with the provisions as outlined shall result in the registered medical practitioner being subject of a complaint under section 57 of the Principal Act by the Medical Council.

Section 3 of the Bill provides the short title and commencement.

1 - Rationale for Bill

In 2016 there was some €6.8 million was given directly to Irish doctors from pharmaceutical companies. The Health Service Executive (HSE) had no record of any of this through the Standards in Public Office Commission.

This obviously poses several ethical issues. Firstly, patients deserve full transparency about how doctors make decisions about recommending new drug treatments for patients. All treatment should be based on international best evidence free of any conflict of interest.

Secondly, given the very large expenditure incurred on medication and other medical goods by the HSE, taxpayers need to know that large financial outlays are solely influenced by clinical outcomes and not by conflicted advice from doctors in receipt of concealed payments from companies in the medical arena.

Thirdly, the Revenue Commissioners ought to be informed about payments of €6.8 million to ensure fair compliance and collection of taxes.

Incidentally, the €10.7 million that went directly to hospitals in from drug companies might not be covered by this Bill. The onus will be on the HSE to regulate this.

Earlier this year the *Irish Independent* reported that drug companies are paying the wages of a significant number of staff in the country's children's hospitals. Our Lady's Hospital in Crumlin confirmed to the newspaper that pharmaceutical companies pay for a nurse and a health and social care worker. Tallaght Hospital also confirmed that there are three junior doctors and two nurses whose salaries are funded by the drug companies.

The Irish Pharmaceutical Healthcare Association does gathers information annually on payments or so-called "transfers of value" by its members companies to doctors but an opt-out clause means many of the recipients are not identified.

According to the Irish Medical Times in 2016 only 55% of doctors who were in receipt of funding from pharmaceutical companies actually declared it.

The Minister for Health ordered a review late last year after claims up to one-third of senior HSE clinicians are in receipt of money from the pharmaceutical companies.

The Health Service Executive responded to the Minister by saying it does not know whether any of its senior staff have received direct payments from pharmaceutical companies.

The HSE investigation failed to establish whether any payments were made and found uncertainty as to whether existing rules were being followed.

The pharmaceutical companies fund posts in many hospitals although the HSE was unable to answer a parliamentary question seeking specific details in February this year. In the reply, the Deputy National Director, Acute Hospital Division said that information requested was "not held centrally by the Acute Hospitals Division" and while the Deputy National Director also "liaised with the hospital groups on this information" it was "not available on a consistent standard format currently".

Professor Michael Barry, of the National Centre for Pharmacoeconomics (NCPE), told the Sunday Business Post in November 2016 that he believes payments from industry are influencing prescribing habits in Ireland. He said doctors were prescribing more costly branded medicines here than doctors in other countries. "What is going on should not be happening. We need to stop making excuses for this," he said.

There are also indications of public support for changing the current situation. A poll on *thejournal.ie* revealed 89 % of respondents did not believe that doctors should continue to receive payments from pharmaceutical companies.

2 - Current Policy and Legislative Context

All positions of employment in the Health Service Executive across all grade categories where the minimum salary point is equal to or above the minimum point of

Grade VIII have been prescribed in regulations as designated positions of employment for the purposes of the Ethics in Public Office Acts 1995 and 2001.

However in view of the fact that the HSE was unable able to answer parliamentary questions submitted and the Health Service Executive response to the Minister for Health that it does not know whether any of its senior staff have received direct payments from pharmaceutical companies and whether existing rules were being followed, it is clear that rules need to be strengthened.

Currently the Medical Council does not ask doctors about any conflicts of interest when they are registering each year.

3 - Sources of Legislation on which bill is modelled

In the United States the Physicians Payments Sunshine Act came into force in 2010. The Sunshine Act, as it is known, requires manufacturers of drugs, medical devices, biological and medical supplies covered by the three federal health care programs Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) to collect and track all financial relationships with physicians and teaching hospitals and to report these data to the Centers for Medicare and Medicaid Services (CMS). The goal of the law is to increase the transparency of financial relationships between health care providers and pharmaceutical manufacturers and to uncover potential conflicts of interest. The bill allows states to enact "additional requirements", as six states already had industry-pay disclosure laws.

France, Portugal, Belgium, Denmark and Slovakia are EU states with primary legislation governing such donations.

In the United Kingdom there is still a huge problem with little clarity on where the money goes. So we would be leading the way in finding a solution to the problem ahead of the National Health Service and the United Kingdom.

The British Daily Telegraph reported on June 30 this year that "Cash and hospitality given by the pharmaceutical industry to doctors has increased to more than £116 million a year, despite a drive to make the practice more transparent. ... Experts ... called for a change in the law to bring Britain in line with the US where doctors are forced to publish all potential conflicts of interest."

Implementation Issues and Considerations

Doctors have to renew their Medical Council registration every year. It's an easy on line process. It will be relatively simple to add a question asking for disclosure on payments on the renewal portal. It may require a little IT work which could then generate an annual report of all submissions made.

The Medical Council will have to inform members of the sanctions faced if they fail to disclose payments. This can be done via its newsletter so it is unlikely to give rise to additional costs.

Financial Implications

This will hopefully have the potential to ensure that the only drug treatments chosen by all doctors are those with clinical efficacy, thereby reducing expenditure on pharmaceuticals nationally.

Declaration of payments could also mean that the Revenue Commissioners will have greater knowledge of any payments and it may serve as a revenue raising measure.