OVERVIEW:

• The NICE/NHSE consultation, “Evaluating and funding drugs and other health technologies”, which closed on 13 January, proposes a budget impact cap on cost-effective cutting-edge technologies.
• Once new technologies are judged cost-effective, it aims to speed up patient access. Under certain cost caps, treatments would automatically be approved. Price negotiations would precede NICE’s final decision.
• The proposed model includes phasing-in cost-effective new technologies, suggesting that full, immediate implementation of NICE recommendations is at an end.
• Responsibility for the unavoidably political decision of “affordability” is also placed in unelected hands.

It proposes:

1. Technologies and treatments (chiefly pharmaceuticals) costing <£10k per quality-adjusted life year (QALY) go through a fast-track NICE appraisal, replacing today’s £20-30k/QALY (with occasional approval over £30k/QALY and £50k/QALY threshold for end-of-life care, mainly for cancer drugs).

2. Rare condition treatments <£100k/QALY funded automatically from routine commissioning budgets. Treatments over £100k/QALY would go through NHSE’s highly specialised technologies process.

3. A £20m ‘budget impact threshold’ for years 1-3.
If NICE approves a new cost-effective technology and years 1-3 will all cost the NHS under £20m, NICE will recommend standard 90-day adoption. Otherwise, cost negotiations will be triggered. If the costs cannot come under this cap, NHS England could ask NICE to extend the 90 days, and phase-in the treatment.

Legally, an approved treatment must become available. But, on the grounds of affordability, some patients would have to wait for phased treatment. But there’s an anomaly. NICE does not review every new technology.
NICE usually reviews drugs expected to cost the NHS the most money. And NICE approval gives them a clear legal advantage over technologies which don’t go through NICE.

Why a £20m cap? It’s not clear. But the Kings Fund reports that in the year to June ‘16, a neat 20% (13) of NICE’s completed 62 technology appraisals were calculated to cost the NHS over £20m in any of the first three years of implementation.

Decisions about NHS budgets are by definition political. NICE was created to make sure new technologies are cost-effective. This would help manage the introduction of very costly new treatments. But deciding on affordability was reserved for ministers.

Ministerial responsibility can be seen in the 2009 creation of a £50k/QALY threshold for end-of-life care and the 2010 Cancer Drugs Fund, which commits to spend more per head on cancer patients, and on approved treatments that NICE said were not cost-effective. These are clearly political decisions about what is affordable.

If the NHS can no longer fund new and cost-effective treatments, NICE should have to ask ministers to decide on phasing-in; not the NHSE. Affordability decisions need to be taken by ministers and to be accountable.